Foreword

With the expansion of antiretroviral therapy (ART) and prevention of mother-to-child HIV transmission (PMTCT) programmes, the estimated number of new HIV infections among children has declined by 41%, from 280,000 in 2010 to 160,000 in 2018(1). Infants who are HIV-infected are at high risk for disease progression in the first year of life. In fact, without treatment, one third of infants with HIV die before they reach one year of age and over 50% die by two years(2). As such, it is critical to initiate HIV-infected infants on ART as early as possible. The key to early access to treatment is early diagnosis of HIV infection. This requires early identification of HIV-exposed infants, HIV testing, and retention of HIV-exposed infants in care to ensure ongoing follow-up with additional testing according to national guidelines, including determination of final HIV status at the end of breastfeeding.

Serological testing (also referred to as antibody testing) cannot confirm HIV infection in infants and children under 18 months of age; instead, infant virological testing through nucleic acid testing (NAT), is required for infant HIV diagnosis. Although virological testing is more costly than serological testing, widespread scale-up has resulted in cost reductions; however, bottlenecks and long turnaround times remain due to delays in sending samples for testing, delays in sample transportation to laboratories, delays in return of results to caregivers, and stock outs. Point of care (PoC) and near PoC NAT has recently been introduced for infant virological testing; this technology has the potential to reduce turnaround time to hours or days rather than weeks or months. This technology offers additional modalities for expanding infant HIV testing services to sites where barriers to conventional NAT have proven most challenging. Issues of quality assurance, site selection for PoC and near PoC platforms, and machine maintenance must be considered prior to implementation.

Since 2010, the World Health Organization (WHO) has recommended that routine NAT of HIV-exposed infants in resource-limited settings should begin at 4–6 weeks of age; this early first test is commonly referred to as early infant diagnosis or EID. WHO also recommends that infants with HIV-negative results be tested again at 9 months of age using a NAT, and again at 18 months of age or 3 months after breastfeeding has ended (whichever is later)(3). In addition, in their 2016 guidelines and 2018 technical report, WHO states that the addition of NAT at birth can be considered where feasible, but only in parallel with efforts to strengthen and expand existing infant HIV testing approaches. Birth testing is an addition to, and does not replace, testing at 4–6 weeks(3, 4).

With the scale up of virological testing of infants, much progress has been made in diagnosing HIV early and providing ART for children. However, in 2018 only 54.9% of newborns exposed to HIV received an HIV test within the first two months of life(5). In addition, over half (54%) of all children living with HIV were accessing treatment in 2018, up from 15% in 2009(6), but still far short of global targets(1).

Overview of the Infant HIV Testing Guides

In 2009, the Centers for Disease Control and Prevention (CDC) released a standardized implementation manual for early infant HIV diagnosis, referred to as the Early Infant Diagnosis of HIV Implementation Guide, to guide programs to plan for and implement these services as part of PMTCT and paediatric HIV-related interventions. This was one among many sets of tools developed to increase the proportion of HIV-exposed infants receiving comprehensive quality care,
including timely infant HIV testing. This book, the 2019 Guide, is an update to the 2009 version; it has been revised based on WHO and other global guidelines released over the last decade and lessons learned from implementation experience. This guide can be adapted according to national guidelines as appropriate. The Guide has now been renamed the Infant HIV Testing Guide, to reflect a focus on the complete cascade of testing for HIV-exposed infants from birth until 18 months of age or 3 months after the end of breastfeeding (whichever is later).

Two books of the Guide have been revised and are released in this 2019 edition:

- Book 1: Implementation Guide for Programme Managers covers programme planning and helps with decisions related to infant HIV testing, including the interface between the clinic and laboratory, monitoring and evaluation, supportive supervision, and linkages between service delivery points. This book focuses on the components that are critical to the management of strong, high quality infant HIV testing services.

- Book 2: Training Curriculum for Healthcare Providers is a complete training curriculum updated with the 2016 and 2018 WHO guidelines. Book 2 also includes jobs aids to support quality infant HIV testing and counselling and early messages to educate women and communities about the comprehensive package of care that all HIV-exposed infants need throughout breastfeeding along with the importance of maternal health and family planning.

Based on the experiences and data shared from years of implementation of infant HIV testing services, the Infant HIV Testing Guide has been revised with the following in mind:

- Infant HIV testing has emerged as an essential service linking PMTCT with paediatric HIV care and treatment.

- Attention has been previously focused on testing at 4–6 weeks of age but HIV testing at this time point is just one component of a cascade of testing that all HIV-exposed infants should receive as part of a comprehensive package of care that does not end until 18 months of age or 3 months after all breastfeeding has stopped (whichever is later) and the child is no longer at risk of HIV transmission.

It is our wish that these books will support countries to scale up and further improve comprehensive care and testing for HIV-exposed infants so that all mothers living with HIV can be supported to prevent HIV transmission to their infants and that infants who become infected are diagnosed early and linked to life-saving treatment.

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Acknowledgements

In 2009, the U.S. Centers for Disease Control and Prevention (CDC) made available the first version of the *Early Infant Diagnosis of HIV Implementation Guide* (now re-titled *Infant HIV Testing Guide*). This 2019 edition of the Guide is divided into two books:

- **Book 1: Implementation Guide for Programme Managers**
- **Book 2: Training Curriculum for Healthcare Providers**

The Guides have been developed and revised with contributions from multiple authors from CDC and other organizations. The original Guide was produced by CDC, authors and contributors included Tracy Creek, Lydia Lu, Michelle McConnell, Chin-Yi Ou, Emilia Rivadeneira, Martha Rodgers, Nathan Shaffer, Shambavi Subbarao, and Amilcar Tanuri. It was later revised with input from CDC and other organizations, including Michelle Adler, Joy Chih-Wei Chang, Helen Dale, Dennis Ellenberger, Sarah Kidd, Olusheyi Lawoyin, Lydia Lu, Mira Mehta, Emilia Rivadeneira, and Nandita Sughandhi,. CDC student interns Meghan Duffy and Allison Doyle facilitated organization of the Guide. The 2019 update of the Guide was led by members of the Maternal and Child Health Branch and the International Laboratory Branch of CDC: Michele Montandon, Helen Dale, Paul Rashad Young, and R. Suzanne Beard. Other contributors to the revised Guide include Gloria Anyalechi, Zena Belay, Ashley Boylan, Sara Forhan, Susan Hrapcak, Mackenzie Hurlston, Kelsey Mirkovic, Surbhi Modi, Monita Patel, Emilia Rivadeneira, and Jason Williams.

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The development of this curriculum was supported through a global technical assistance grant from CDC, number U2GPH000994. These materials are in the public domain, and we hope that they can play a useful role as part of the ever-expanding “toolbox” of guidelines and manuals being developed to support PMTCT and HIV-exposed infant care, including infant HIV testing, globally. These manuals may be freely modified and adapted to country programs needs and to changes in technology, policy, and guidelines.
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### Acronyms

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<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Ag</td>
<td>Antigen</td>
</tr>
<tr>
<td>ANC</td>
<td>Antenatal care</td>
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<tr>
<td>ART</td>
<td>Antiretroviral therapy</td>
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<tr>
<td>ARV</td>
<td>Antiretroviral</td>
</tr>
<tr>
<td>AZT</td>
<td>Zidovudine</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacillus Calmette–Guérin</td>
</tr>
<tr>
<td>CAB</td>
<td>Client/consumer/community advisory board</td>
</tr>
<tr>
<td>CD4</td>
<td>T-lymphocyte CD4 cell count</td>
</tr>
<tr>
<td>CDC</td>
<td>U.S. Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CE-IVD</td>
<td>Conformité Européene-In-Vitro Diagnostic</td>
</tr>
<tr>
<td>CT</td>
<td>Cycle threshold</td>
</tr>
<tr>
<td>DBS</td>
<td>Dried blood spots</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid (genetic material)</td>
</tr>
<tr>
<td>EDTA</td>
<td>Ethylenediamine tetraacetic acid</td>
</tr>
<tr>
<td>EID</td>
<td>Early infant diagnosis</td>
</tr>
<tr>
<td>ePNP</td>
<td>Enhanced postnatal prophylaxis</td>
</tr>
<tr>
<td>EQA</td>
<td>External quality assurance</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
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<tr>
<td>HEI</td>
<td>HIV-exposed infant</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>ID</td>
<td>Identifier</td>
</tr>
<tr>
<td>LIS</td>
<td>Laboratory information systems</td>
</tr>
<tr>
<td>LTFU</td>
<td>Lost to follow up</td>
</tr>
<tr>
<td>MCH</td>
<td>Maternal Child Health</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of health</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of understanding</td>
</tr>
<tr>
<td>MTCT</td>
<td>Mother-to-child transmission (of HIV)</td>
</tr>
<tr>
<td>NAT</td>
<td>Nucleic acid testing</td>
</tr>
<tr>
<td>NVP</td>
<td>Nevirapine</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>President's Emergency Plan For AIDS Relief</td>
</tr>
<tr>
<td>PMTCT</td>
<td>Prevention of mother-to-child transmission (of HIV)</td>
</tr>
<tr>
<td>PoC</td>
<td>Point of Care or near PoC</td>
</tr>
<tr>
<td>PPV</td>
<td>Positive predictive value</td>
</tr>
<tr>
<td>PT</td>
<td>Proficiency testing</td>
</tr>
<tr>
<td>QA</td>
<td>Quality assurance</td>
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<tr>
<td>QC</td>
<td>Quality control</td>
</tr>
<tr>
<td>QI</td>
<td>Quality improvement</td>
</tr>
<tr>
<td>RDT</td>
<td>Rapid diagnostic testing</td>
</tr>
<tr>
<td>RNA</td>
<td>Ribonucleic acid (genetic material)</td>
</tr>
<tr>
<td>SIMS</td>
<td>Site Improvement Through Monitoring System</td>
</tr>
<tr>
<td>SMS</td>
<td>Short message service</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard operating procedure</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>TNA</td>
<td>Total nucleic acid</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
</tr>
<tr>
<td>Us</td>
<td>Ultrasensitive</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>VL</td>
<td>Viral load</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
Overview of *Infant HIV Testing Implementation Guide for Programme Managers*

*Infant HIV Testing Implementation Guide for Programme Managers* aims to improve infant HIV testing programme performance and improve care and outcomes for HIV-exposed infants by providing Programme Managers with information, advice, resources and tools to support and guide the implementation and improvement of local, health facility-level infant HIV testing services. This Guide is targeted primarily to the sub-national Programme Manager, i.e., the Programme Manager responsible for planning, implementing, monitoring and evaluating infant HIV testing services at a local, district, regional/zonal, or state level. It is our hope to empower the sub-national Programme Manager to work within communities and health facilities and with healthcare providers to support achievement of infant HIV testing targets.

This updated *Implementation Guide for Programme Managers* provides subnational Programme Managers with background science as an update on virological testing and a briefing on the key elements of successful infant HIV testing programmes. These key elements are:

- Clear national guidelines and testing algorithm
- Monitoring and evaluation systems
- Identification of HIV-exposed infants
- Retention in care
- Healthcare provider selection and training
- Ongoing supervision and quality improvement
- Laboratory practices
- Sample transport and results return
- Forecasting and supply chain management
- Linkage of HIV-infected infants to antiretroviral therapy
- Community engagement

The appendices provide additional information and tools to support Programme Managers in their work to ensure that infant HIV testing services are of high quality and succeed in saving the lives of children who are HIV-exposed and HIV-infected.

**Target Population**

This *Implementation Guide for Programme Managers* was written for managers responsible for the planning, implementation, monitoring and evaluation of infant HIV testing services on the sub-national — e.g., district, regional/zonal, or state — level. This Programme Manager is likely to work under the guidance of the national programme manager and responsible for one clinic or many health facilities that provide services to infants and their caregivers: child immunization services, maternal-child health clinics, as well as the higher-level care that meets the needs of sick infants: HIV care and treatment clinics, tuberculosis clinics, malnutrition services, and other inpatient and outpatient services. We recognize that some Programme Managers will be responsible for infant HIV testing programme planning as their core and, perhaps, only function, others will be responsible for a range of clinical and administrative duties that includes infant HIV testing programme planning.
Additional resources: National or sub-national Programme Managers responsible for HIV clinical services including PMTCT and paediatric HIV services should also refer to the following resources:

  https://www.childrenandaids.org/sites/default/files/2017-05/IATT-Toolkit-Dec-2014_JR-1-28-15-Web1.pdf Although this toolkit was written to support the rollout of Option B/B+, most of the resource is applicable to Programme Managers supporting the scale up of universal access to ART and PMTCT, as recommended in the WHO’s 2016 HIV Treatment Guidelines(4). Section 3 of the Toolkit, Moving Towards Expanded HIV Services for Children: Readiness Assessment Checklist and Discussion Guide, supports the assessment of readiness of health systems to improve care and treatment of children.

Terminology

Within this guide, the following terms will be used:

- **Nucleic acid testing (NAT):** an infant virologic testing procedure that diagnoses infection by detection of HIV virus nucleic acid. NAT detects DNA, RNA or both. NAT uses polymerase chain reaction (PCR) technology, and is sometimes referred to as PCR testing.
- **Infant HIV testing:** any HIV test included in the testing algorithm; this includes NAT (virologic) and rapid diagnostic testing (serologic testing).
- **Early infant diagnosis (EID):** a virologic test at 4–6 weeks of age or earlier for diagnosis of HIV infection; EID is one component of the infant HIV testing cascade.
- **Birth testing:** a test at or around birth (0–2 days) which complements current 4–6 week testing but should not be considered a replacement to it
- **PoC testing:** PoC testing is when patients are tested on-site at a health facility and receive their results during the same visit or day. Testing at PoC brings test results closer to the patient(7).
- **Near PoC testing:** Near PoC testing is when PoC technology is located at a health facility, district or other non-central laboratory where needed infrastructure (such as electricity) is consistently accessible(7).
- **Conventional testing** refers to the conventional diagnostic technologies located in the central or regional laboratories that make up the backbone of national testing services. These technologies require sophisticated laboratory infrastructure, stable electricity supply, and highly trained technicians(7).
- **HIV-exposed infant care:** a comprehensive package of care that all HIV-exposed infants should receive (see page 12–13); HIV testing is just one component of HIV-exposed infant care and EID is just one component of the infant HIV testing cascade.

Scaling up Infant HIV Testing Services

Without treatment, HIV-infected children rapidly progress to AIDS, with about 50% dying before their second birthday. Experience has shown that early treatment can significantly improve the quality of life and life expectancy for HIV-infected children(8). As resource-limited countries develop capacity to manage HIV-infected children, and as paediatric antiretroviral therapy (ART) becomes more available, it is critical to develop systems for the early diagnosis of HIV infection to
significantly reduce HIV-related morbidity and mortality in the first years of life. The World Health Organization (WHO) recommends that every infant or child diagnosed with HIV receive ART immediately, even if apparently healthy(4).

Infants acquire HIV infection most commonly through mother-to-child transmission (MTCT) during pregnancy, childbirth, or breastfeeding. A variety of interventions can reduce the risk of MTCT, namely lifelong ART for pregnant and breastfeeding women living with HIV, but also improved obstetric practices, 6–12 week regimen of antiretroviral (ARV) medication for HIV-exposed infants (depending on risk), and appropriate approaches to infant feeding. Over the past decade, many countries have launched prevention of mother-to-child transmission (PMTCT) programmes that are integrated into existing maternal, child health (MCH) settings. While these programmes have been relatively successful in identifying HIV-positive pregnant women, success at reducing MTCT is difficult to establish without systematic testing of all exposed infants. In most settings, follow up of HIV-positive mothers and HIV-exposed infants has been below target levels. Furthermore, infants with first negative EID are lost to follow-up before determination of final infection status at the end of breastfeeding. Most HIV-infected infants are not identified early, so most programmes do not know their MTCT rate. Timely infant HIV testing can help HIV-infected infants access lifesaving treatment, provide reassurance for families of uninfected infants, and help MCH programmes monitor the effectiveness of their PMTCT interventions.

Challenges to the scale up of infant HIV testing services
Challenges in establishing and managing infant HIV testing services include:

- Establishing service delivery models that facilitate systematic early identification and retention in care of all HIV-exposed infants and their mothers through the end of the breastfeeding period to ensure the mother-infant pair is provided with essential HIV services, including HIV testing and treatment.
- Establishing reliable follow-up systems whereby HIV-exposed infants who miss appointments can be quickly identified, traced, and returned to care and HIV-infected infants can be located, linked to care and treatment services, and quickly initiated on ART.
- Establishing the infrastructure and technical capacity needed to ensure highly accessible, uninterrupted, quality NAT services. Ensuring the parallel development of capacity to both diagnose and ensure early initiation of ART(9).
- Establishing a reliable transport network for infant dried blood spot (DBS) samples and laboratory results.
- Ensuring the return of HIV test results to their caregivers in a timely manner.
- Supporting strong, clear documentation and data systems to provide quality programme data for monitoring and evaluation of programme performance and quality improvement (QI).
- Supporting and building the capacity of MCH staff to stay abreast of programme changes and engage in continuous QI, providing excellence in counselling and service quality to families affected by HIV.

Systematic identification and retention in care of HIV-exposed infants and their mothers has not been easy for most PMTCT programmes. In many settings, information about the HIV status of the mother and PMTCT interventions received is not recorded on the child health card. This makes it difficult to identify the HIV-exposed infant to ensure the delivery of comprehensive care. Critical opportunities to reduce the risk of transmission and diagnose HIV early so that ART can be
provided to those who are HIV infected in a timely manner are frequently missed. The aim of this Guide is to support Programme Managers to implement national recommendations at the health facility level to ensure that infants whose mothers are living with HIV remain HIV-free and that the rare infant who does acquire HIV is immediately initiated on ART.

**Comprehensive Package of Care for HIV-Exposed Infants**

To be successful, initiatives to expand and improve infant HIV testing services need to be part of wider efforts to provide all HIV-exposed infants with a comprehensive package of care starting at birth and continuing through the breastfeeding period and to ensure HIV-infected infants are immediately linked to ART. A holistic approach to the care of HIV-exposed infants will maximize the chances of ensuring all HIV-exposed infants are tested by 4–6 weeks of age, receive comprehensive care and testing services throughout breastfeeding, and ultimately have a final HIV status at either 18 months of age or 3 months after breastfeeding (whichever is later). This will require the commitment and collaboration of clinical and laboratory staff and public health programme managers but is an opportunity to optimize care of HIV-exposed infants, assure early access to ART for HIV-infected children, provide reassurance for the many families of uninfected children, monitor PMTCT programme effectiveness, and transfer and build capacity of key laboratory technologies.

**The comprehensive package of care includes:**
1. Identification of HIV-exposed infants (discussed in Section 3 of this Guide) and infant HIV testing
   - HIV testing at 4–6 weeks of age, 9 months, and 3 months after cessation of breastfeeding and immediate initiation of ART for those identified as infected. (Note: Some sites/countries may have introduced birth testing in addition to the testing listed above. If birth testing is provided, it is still very important that infants are also tested at 4–6 weeks.)
2. Preventive medical care
   - Infant ARV prophylaxis: Daily oral medication to prevent HIV infection from birth to 6–12 weeks of age, depending on risk of infection. Infants considered high risk (see text box) should receive enhanced postnatal prophylaxis (ePNP). ePNP refers to:
     - First 6 weeks: dual drug prophylaxis (zidovudine [AZT] plus nevirapine [NVP])
     - Second 6 weeks (breastfeeding infants only): either AZT plus NVP or NVP alone
   - Healthcare providers should support caregivers to administer infant ARV prophylaxis:
     - Discuss recommendations for ARV prophylaxis based on infant age and risk category, prescribe ARV prophylaxis if indicated.
     - Provide counselling and support.

**High-risk HIV-exposed infants**

WHO defines “high-risk” as infants born to women with HIV who:
- Received less than 4 weeks of ART at time of delivery or no ART OR
- Have a viral load (VL) >1000 copies/mL in the 4 weeks before delivery, OR
- Were born to women with incident HIV infection during pregnancy or breastfeeding OR
- Were born to women diagnosed with HIV at delivery or postpartum(10).

See Appendix 1 for more information.
• Cotrimoxazole prophylaxis: Daily medication (cotrimoxazole) starting at 4–6 weeks of age until final HIV status is established at least 3 months after stopping breastfeeding, to prevent illness and death due to diarrhoea, malaria, and pneumonia among HIV-exposed infants.
• Tuberculosis (TB) screening and TB preventive therapy for infants in contact with active TB cases. Provide isoniazid preventive therapy (IPT) if the infant does not have active TB disease but has known contact with a person with TB disease.

3. Routine infant care
• Immunizations: It is particularly important for these children to be immunized completely and on time because of their vulnerability to infection. Provide the same immunizations for HIV-exposed and HIV-infected infants as for those who are not exposed, except infants who are known HIV-infected or have signs/symptoms consistent with HIV should not receive bacillus Calmette–Guérin (BCG) vaccine. This recommendation is based on 1) the risk of disseminated BCG disease in children infected with HIV vaccinated at birth and 2) the vaccine may provide little, if any, protection against TB in HIV-infected infants because HIV infection appears to impair the BCG-specific T-cell responses(11). Note: HIV-exposed infants who are not known HIV positive at birth and are not born with signs of HIV should receive BCG vaccine.
• Growth monitoring and nutritional support
• Developmental screening
• Infant feeding counselling to promote exclusive breastfeeding for the first 6 months of life

4. Family care and support
• Ensure maternal ART adherence and maternal viral suppression at routine intervals during pregnancy and breastfeeding. Ensure mother’s adherence to lifelong ART.
• Psychosocial support and caregiver counselling and education on postnatal care and HIV-exposed infant services.
• Family HIV testing: Sexual partners and other biological children.
• Male partner engagement in healthcare services.
• Family planning.

5. Community linkages and referrals (discussed in “Section 10: Linkage of HIV-infected Infants to ART”)
6. Tracking of mother-infant pair for missed appointments and loss to follow-up (discussed in “Section 4: Retention in Care”)
7. Linkage with community-based support systems and support groups
8. Referral to social welfare programs (e.g., orphans and vulnerable children services)(12)

Additional considerations for comprehensive HIV-exposed infant care include:
• **Integration into child immunization services**: the comprehensive package of care for HIV-exposed infants can occur on the same schedule as immunizations and routine growth monitoring. For example, the first postnatal visit (4–6 weeks) occurs before most HIV-infected infants become ill and offers an ideal opportunity for infant HIV testing and initiation of cotrimoxazole. (For more information on the care of HIV-exposed infants, see Module 3 of Book 2, *Training Curriculum for Healthcare Providers*.)
• **Linking mother and infant care**: The care of the breastfeeding infant should be linked to the care of the mother. The mother-infant pair should receive their care together whenever possible because optimal outcomes for the baby are dependent on the health and viral suppression of the
mother. Maternal adherence and retention on lifelong ART can prevent HIV transmission in the current and future pregnancies.

- **Adherence to care and patient tracking:** Given that HIV-exposed infants are at increased risk of malnutrition, illness, and death (even if not HIV-infected) it is important that they attend all clinic visits, are provided with focused examinations at each visit, and are provided with counselling to support safe feeding (discussed in the next session). Mothers and infants who miss appointments should be traced and counselled on the importance of returning to care.

**Introduction to the Key Elements of Successful Infant HIV Testing Programmes**

Every country’s approach to establishing and strengthening infant HIV testing services is unique. Some are driven by MCH programmes, others by laboratory services. Some integrate screening for HIV-exposed infants into well-child services; some rely on dedicated teams of HIV-specific services providers for follow up. Some are championed by one national effort, and others involve the collaboration of multiple partners. Despite differing approaches, common elements have emerged as necessary standards to all successful programmes. Based on the experiences of multiple country programmes, CDC has distilled 11 key elements of successful infant HIV testing services. Each of the 11 key elements will be explained in this manual.
Figure 1: Key elements of successful infant HIV testing services

1. Clear national guidelines and testing algorithm
2. Monitoring and evaluation systems
3. Identification of HIV-exposed infants
4. Retention in care
5. Healthcare provider selection and training
6. Ongoing supervision and QI
7. Laboratory practices
8. Sample transport and results return
9. Forecasting and supply chain management
10. Linkage of HIV-infected infants to ART
11. Community Engagement

Key elements of successful infant HIV testing programmes
Infant HIV testing services: what works

In the decade since infant HIV testing programmes were initiated, programmes that include the following services tend to be most effective in finding, testing and caring for HIV-exposed infants:

- Interdisciplinary task team that takes the lead on planning infant HIV testing services. This task team would include representation from the laboratory, HIV clinical programs (PMTCT and HIV care and treatment), logistics/supply chain, monitoring and evaluation, and other relevant stakeholders. The task team would take the lead on the strategic planning of the implementation of infant HIV testing and ensure collaboration and smooth functioning of services at the patient-level.
- Coordination between antenatal and postnatal care, PMTCT services, child health programmes (nutrition, immunizations, and ill-child care), programmes for orphans and vulnerable children, and paediatric and adult ART services is essential.
- Routine testing of all known HIV-exposed infants for HIV at 4–6 weeks of age and again at 9 months of age and 18 months of age or 3 months after cessation of breastfeeding (whichever is later). Some programs are also testing HIV-exposed infants at birth.
- Assessment of infant HIV exposure status (maternal HIV status) and HIV testing for HIV-exposed infants at immunization and outpatient clinic visits in generalized epidemics.
- Routine testing of all infants and children at high yield service delivery points (TB clinic, malnutrition, inpatient wards) with unknown HIV status; HIV testing for all infants and children with signs and symptoms of HIV.
- Careful planning with, and adequate funding for, laboratory training, infrastructure, equipment, and supplies.
- Updated child health cards and patient medical charts to include HIV and PMTCT information to facilitate identification of HIV-exposed infants for follow-up, including HIV testing services.
- Simplified HIV testing specimen collection methods, including finger prick for rapid diagnostic tests (RDTs) and heel, toe, or finger prick for DBS specimen collection. This avoids the need for venipuncture, decreases the risk of accidental needle stick injuries, and simplifies sample storage and transportation.
- Provision of the comprehensive package of care for HIV-exposed infants (see page 12–13).
1. Clear National Guidelines and Testing Algorithm

National guidelines

Clear national infant HIV testing guidelines are critical because they drive programme practice, standards and expectations of infant HIV testing services. Country infant HIV testing guidelines:

- Define the goal, objectives, and targets of infant HIV testing services.
- Define who will benefit from the services (age, clinical status, etc.), and what services they will receive.
- Communicate where services will be provided.
- Support the planning, training, support, and management of staffing.
- Support the planning, implementation, and evaluation of commodity forecasting, logistics, and supply chain needed to support the service.
- Communicate a consistent philosophy, establish standards, and drive programme practices and expectations. This supports nation-wide standardization of services.
- Describe how infants of unknown HIV-exposure status will be identified.
- Describe which tests (type of test and manufacturer) will be used and when each will be used. List which cadre of healthcare provider will be allowed to provide pre-test information, post-test counselling, and administer the testing procedure.
- Include a testing algorithm. Additional tools may include clinical algorithms for HIV-exposed infants, and tools to support clinical assessment and to assist with diagnosis.
- Describe how infant HIV test results will be returned to caregivers.
- Set criteria for initiating ART in infants, children, adolescents, and adults.
- Outline how programme success (outcomes) will be measured and describe how services will be monitored and evaluated and the tools to be used for this purpose.

It is recommended that each region/district have an interdisciplinary task team that includes representation from laboratory, HIV clinical programs (PMTCT and HIV care and treatment), logistics/supply chain, monitoring and evaluation, and other relevant stakeholders. The work of this task team may include:

- Implementation of national guidelines, achievement of local targets and QI.
- Adherence to standards of procedure outlined in the national guidelines.
- Local protocol to achieve national targets and local targets that may not be listed in the national guidelines (e.g., how infant HIV test results will be returned to caregiver, how wait times will be reduced, etc.).
- Coordination of local services, particularly linkages between agencies that ensure clients have access to the full continuum of care.
- Training and support of staff.
- Local issues on transporting specimens to the laboratory and the timely return of results.
- Local issues on commodities, storage, stock-taking, and budgeting.

Global recommendations

National infant HIV testing recommendations are typically based on global recommendations, e.g., WHO guidelines, and adapted for country-specific circumstances, including the health system, national budgets, and locally determined priorities and standards. The most recent global
recommendations from WHO applicable to HIV-exposed and -infected infants and children appear in Table 1 and Table 2, below.

**Table 1: Key testing-related recommendations from WHO regarding infants and children**

<table>
<thead>
<tr>
<th>Laboratory testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• It is strongly recommended that <strong>HIV serological assays</strong> used for clinical diagnostic testing have a minimum sensitivity of 99% and specificity of 98% under quality-assured laboratory conditions.</td>
</tr>
<tr>
<td>• It is strongly recommended that <strong>HIV virological assays</strong> used for the purpose of clinical diagnostic testing (usually at or after 6 weeks of age) have a sensitivity of at least 95% and ideally greater than 98%, and specificity of 98% or more under quality-assured, standardized, and validated laboratory conditions.</td>
</tr>
<tr>
<td>• It is strongly recommended that <strong>HIV virological testing</strong> be used to diagnose HIV infection in infants and children below 18 months of age.</td>
</tr>
<tr>
<td>• In infants and children undergoing virological testing, the following assays (and respective specimen types) are strongly recommended for use: HIV DNA on whole blood specimen or DBS; HIV RNA on whole blood, plasma or DBS; ultrasensitive p24 antigen (Us p24 Ag) on plasma or DBS.</td>
</tr>
<tr>
<td>• Any indeterminate test results should be repeated on the same sample using additional DBS or whole blood before contacting the health facility to request the infant return to the facility for collection of a new sample of blood.</td>
</tr>
<tr>
<td>• PoC testing can be used to confirm positive test results.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Timing of testing, type of test &amp; return of results</th>
</tr>
</thead>
<tbody>
<tr>
<td>• It is strongly recommended that all HIV-exposed infants have <strong>HIV virological testing at 4–6 weeks of age</strong> or at the earliest opportunity thereafter.</td>
</tr>
<tr>
<td>• It is strongly recommended that test results from virological testing in infants be returned to the clinic and child/mother/caregiver as soon as possible, but at the very latest within 4 weeks of specimen collection. Positive test results should be fast-tracked to the mother–baby pair as soon as possible to enable prompt initiation of ART.</td>
</tr>
<tr>
<td>• It is strongly recommended that HIV-exposed infants who are well undergo <strong>HIV testing at around 9 months of age</strong>. NAT is recommended; however, if using rapid diagnostic tests (RDTs) (rather than virological testing), infants who test positive should have a virological test to diagnose HIV infection(3).</td>
</tr>
<tr>
<td>• It is strongly recommended that <strong>infants with signs or symptoms</strong> suggestive of HIV infection undergo HIV testing.</td>
</tr>
<tr>
<td>• It is strongly recommended that <strong>children (18 months or older) with suspected HIV infection or HIV exposure have HIV serological testing</strong> performed according to the standard diagnostic HIV serological testing algorithm used in adults.</td>
</tr>
<tr>
<td>• Addition of <strong>NAT at birth</strong> to existing EID testing approaches can be considered to identify HIV infection in HIV-exposed infants.</td>
</tr>
</tbody>
</table>

Use of rapid diagnostic testing for infants:
- RDTs for HIV serology can be used to assess HIV exposure only in infants less than 4 months of age. HIV-exposure status in infants and children 4–18 months of age should be ascertained by undertaking HIV serological testing of the mother.
- Rapid diagnostic tests for HIV serology can be used at 9 months to rule out HIV infection in asymptomatic HIV-exposed infants.

### Initiation of ART and confirmatory testing

- In infants with an initial positive virological test result, it is strongly recommended that **ART be started without delay** and, at the same time, a second specimen is collected to confirm the initial positive virological test result. Do not delay ART. Immediate initiation of ART saves lives and should not be delayed while waiting for the results of the confirmatory test.
- ART regimens for infants are listed in Appendix 2.

### Provider-initiated HIV testing and counselling for infants and children

- It is strongly recommended that all infants with unknown or uncertain HIV exposure seen in healthcare facilities at or around birth or at the first postnatal visit (usually 4–6 weeks) or other child health visit have their HIV exposure status ascertained through maternal testing. (See “Strategies for identification of the HIV-exposed infant” in “Section 3: Identification of HIV-exposed Infants.”)
- In generalized epidemic settings, infants and children with unknown HIV status who are admitted for inpatient care or attending malnutrition clinics should be routinely tested for HIV.
- In generalized epidemics settings, infants and children with unknown HIV status should be offered HIV testing in outpatient or immunization clinics.

### Point-of-care technologies for the diagnosis of HIV infection in infants and children

- NAT technologies that are developed and validated for use at or near to the point of care (PoC) can be used for infant HIV testing. PoC NAT testing can also be used for confirmation of initial positive test results.

Adapted from: WHO, 2016 (4) and WHO, 2018 (3).
Table 2: HIV testing by age, WHO recommendations

<table>
<thead>
<tr>
<th>Category and age</th>
<th>Recommended test</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-exposed infant, at birth (0–2 days), provide testing if recommended by national guidelines</td>
<td>HIV virological testing using NAT, as per national guidelines</td>
</tr>
<tr>
<td>HIV-exposed infant, at 4–6 weeks of age, or as soon as possible thereafter</td>
<td>HIV virological testing, using NAT</td>
</tr>
<tr>
<td>HIV-exposed infant, at 9 months of age</td>
<td>HIV virological testing, using NAT *</td>
</tr>
<tr>
<td>HIV-exposed infant, at 18 months of age or 3 months after breastfeeding ends (whichever is later) for final assessment of HIV status</td>
<td>HIV serological testing if 18 months of age or older; HIV virologic testing if final test prior to 18 months of age (requires breastfeeding cessation prior to 15 months of age)</td>
</tr>
</tbody>
</table>

* Prior to July 2018, WHO recommended HIV serological testing of HIV-exposed infants who were 9 months of age. If positive, they then recommended virological testing using NAT. WHO now recommends using NAT for infants 9 months of age due to concerns about ability of an antibody test to identify all HIV-infected infants and to minimize “the challenges of interpretation and simplify the infant testing algorithm.” (3)

**HIV testing algorithm**

Algorithms are defined as the combination and sequence of specific tests used in a given strategy. Testing algorithms are typically developed at a national level and, like clinical guidelines, often based on global guidance. Development of a country-specific testing algorithm must take into account a number of factors, including test performance, local prevalence of HIV infection, test availability in country, ease of use, type of specimen and collection method, cost, and potential need to differentiate between HIV-1 and HIV-2. Interpretation of this algorithm for clinical use requires consideration of HIV treatment criteria, age of the child, and ongoing exposure to HIV through breastfeeding.

**Importance of national testing algorithms.** Nationally adopted testing strategies and algorithms facilitate:

- Country-level standardization of tests: Supporting a limited number of tests is more feasible and practical than many different tests.
- Procurement and supply management: using standardized tests allows for bulk procurement, which facilitates cost control.
- Training: Implementation of a national training programme is easier when test sites follow the same testing algorithm and it allows trained staff to move between sites/regions without requiring re-training.
- Quality assurance (QA): National oversight of quality of testing operations is easier when test sites use the same tests and have similar operations.

The WHO Infant Testing Algorithm (from July 2018 Technical Report. HIV Diagnosis and ARV Use in HIV-Exposed Infants: A Programmatic Update from WHO) is included as Appendix 3.
Birth testing
In their 2016 guidelines, WHO described NAT at or around birth (within the first 2 days of life) as having potential benefits “as it provides an additional opportunity for testing and enables earlier identification of infected infants”(4). However, there has been limited experience implementing birth testing outside a small number of countries.

HIV testing of infants at birth is most likely to identify infants infected in utero and at greatest risk for early mortality. Birth testing will not detect infections that may have taken place during or shortly after delivery. In contrast, 4–6 week testing will identify infants who acquired the infection in utero, during delivery, or in the early postpartum period. Therefore, a NAT at birth can be added to a routine 4–6 week test, however it does not replace the 4–6 week test. WHO recommends that countries ensure their routine EID at 4–6 weeks of age is high functioning with good coverage and excellent follow up before adding a birth test.

Potential advantages of birth testing: Birth testing provides an earlier opportunity to diagnose HIV in infants who acquired the infection in utero. This, in turn, provides an earlier opportunity to start ART; data suggests that infants testing positive at birth, start ART on average two months earlier than non-birth tested infants(13). This is important because infants infected in utero or intrapartum are at a higher risk of early death. Studies suggest that 30–40% of these babies will die by 3 months of age(4).

Potential challenges of birth testing:
• Reduced uptake of 4–6 week testing: To minimize this disadvantage, countries must develop clear standardized counselling messages that emphasize to parents of HIV-exposed infants testing HIV-negative the importance of repeat testing at 4–6 weeks of age, 9 months, and again at 18 months of age (or 3 months after breastfeeding cessation, whichever is later).
• Cannot detect all perinatal infections: Birth testing will only detect in utero infections; therefore, infections that occurred during delivery or shortly after birth through early breastfeeding will not be identified with birth testing. In addition, the presence of ARVs (maternal or infant) may reduce the ability of NAT to detect infant HIV infection. Two recent studies found that birth testing with NAT identifies only about 2 of every 3 infants who are infected(4). This highlights the importance of retention in care and repeat testing at 4–6 weeks of age.
• False-positive results: Although the specificity of NAT is high, more truly HIV-negative babies will erroneously test HIV-positive at birth (false positives) in comparison to 4–6 weeks of age. This is because the prevalence of HIV infection at birth is lower than at 4–6 week of age, highlighting the need for confirmatory testing. However, ART initiation should not be delayed(4).
• Linkage of infected infants to ART: HIV-infected women often access maternity services at locations distant from home. This can pose a barrier to successful long-term linkages to ART services for infected infants identified at birth. In addition, treatment of very young infants requires infant-friendly formulations and complex regimen switches based on age; and, there is limited data on dosing and regimen choices for premature and low birth weight newborns.

Who receives a test at birth? Some countries are starting to implement birth testing. Countries considering the addition of a birth test are implementing either of two approaches:
• Universal testing of all HIV-exposed infants at maternity or within 48 hours postpartum.
• Testing of high-risk HIV-exposed infants, also called targeted testing (“high risk” is defined on page 12). However, in a busy maternity setting it can be difficult for healthcare providers to identify high-risk infants for targeted testing. A study in South Africa(14) found only about a fifth of infants eligible for birth testing received testing when South African guidelines restricted birth testing to only high-risk infants (defined as maternal ART <3 months at delivery, maternal VL >1000 copies/ml, infant <37 weeks gestation, infant <2.5 kg).

Both approaches have advantages and disadvantages — targeted testing may reduce costs, yield a higher rate of HIV-positive results, and less work. However, targeted testing will miss HIV-infected infants assumed to be low risk.

Planning for implementation of birth testing. Birth testing is being scaled up in South Africa and piloted in Kenya, Democratic Republic of the Congo, Zimbabwe, and Eswatini(3). Based on lessons learned in these countries it is known that the scale up requires meticulous planning, innovation, and supervision. National and local consideration in the implementation of birth testing include:

• Critical review of current EID performance and maternity delivery rates to assess the benefit of adding birth testing to the current HIV infant testing programme. In situations where the attended delivery rate is lower than early immunization coverage (e.g. 6 weeks of age), the added value of birth testing will be limited.

• Revision of national guidelines, including the development of revised standard operating procedures (SOPs) and new/revised tools (e.g., registers and electronic databases to document testing activities and results and to track patients) and the training of healthcare providers on the new guidelines.

• Phased implementation: Countries that are considering the implementation of birth testing are implementing it first in a limited number of health facilities in several different regions to research acceptability and identify the best system to ensure timely testing, results delivery, linkage to ART, and healthcare provider training needed for successful implementation.

• Programme monitoring and evaluation systems are needed: these systems should mirror the monitoring and evaluation systems for existing infant HIV testing interventions. For birth testing, monitoring is also important to measure cost-effectiveness and whether birth testing influences uptake of HIV testing at 4–6 weeks of age.

• Financial investment to pay for the hiring and training of hospital and community-based staff (counsellors, nurses, data-capturers) to identify infants for testing, provide pre-test information, obtain blood sample and provide results. Funding for the purchase of equipment and consumables to process additional specimens using NAT; redesign of data collection tools/registers for monitoring, evaluation and patient tracking.

• SOPs for birth testing: SOPs should specify where, when and how birth testing will occur. SOPs should be used in training of health care workers and readily available in the health care facility. SOPs should address issues specific to birth testing such as increased human resources needed, the difficulty of collecting blood samples in newborns, the need to ensure sample collection outside of standard working hours and deliver results, linkage to ART and the nature of the EID system as a whole (stock outs, referral mechanisms, delayed results).

• Turnaround time: ensure turnaround time for reporting test results to health facilities and caregivers is rapid to optimize the benefit of NAT at birth. PoC assays should be used where available.
• **Patient-tracking procedures** to return results to caregivers as soon as results are available and to track patients who fail to show for their post-test session or for testing at 4–6 weeks of age.

• **Identification of eligible patients**: SOPs to identify all HIV-positive women at time of delivery (maternal retesting) and then identify HIV-exposed infants eligible for testing.

• **Development of ART recommendations for HIV-infected newborns**: Guidelines for newborn ART are complex because only a limited number of ARVs can be used in the first weeks of life and there is limited global experience with ART for newborns. See “Appendix 2: First-Line Regimens for Paediatric Populations”.

Birth testing must never replace routine testing at 4–6 weeks, 9 months, and at 18 months or 3 months after breastfeeding cessation (whichever is later). WHO stressed in their recommendations that birth testing should only be considered where infant HIV testing at 4–6 weeks of age is well established. It is important to note that where birth testing is being established, it is in addition to testing at 4–6 weeks, 9 months, and at 18 months or 3 months after breastfeeding cessation, and it should only be implemented in parallel with strengthening of existing infant HIV testing services.

**Programme Manager’s role**

It may be the responsibility of the sub-national Programme Manager to convene an interdisciplinary task team to ensure national guidelines and algorithms are fully implemented and to address implementation challenges. The Programme Manager might also be expected to ensure local practice meets nationally determined standards through audit.

2. **Monitoring and Evaluation Systems**

According to WHO(15), monitoring and evaluation:

- Provides information on how well an intervention is performing and whether it is achieving its aims and objectives;
- Offers guidance on future intervention activities;
- Are an important part of accountability to funding agencies and stakeholders.

**Monitoring**

Monitoring is the routine, everyday collection of information about project activities. Information from monitoring indicates whether things are going according to plan and helps project managers identify and solve problems quickly. Monitoring tracks project inputs and outputs such as:

- Activities (e.g., services provided such as number of infants tested, number positive and negative results)
- Reporting and documentation
- Finances and budgets
- Supplies and equipment

**Evaluation**
An **evaluation** asks whether a project is achieving what it set out to do, and whether it is making a difference. Evaluations typically take place before an intervention is initiated (for baseline data) and then after the first year and then every 2 or 3 years. Although project staff are responsible for recording work-related activities, evaluation can be conducted by external agencies or by project staff.

**Data sources**

**(1) Registers.** Infant HIV testing data is usually recorded in paper-based registers or electronic record systems/databases designed at the national level. Some countries have developed dedicated HIV-exposed infant birth cohort monitoring registers, which follow HIV-exposed infants longitudinally from birth until final HIV status is confirmed at 18 months or at least 3 months after breastfeeding cessation (whichever is later). Other countries include infant HIV testing columns/fields in infant or mother-baby registers (see Appendix 4: Register Examples: Integrated Mother-Baby Pair Register and HIV-Exposed Infant Birth Cohort Register). Some countries using integrated MCH/PMTCT registers will also have a DBS Specimen Tracking Register or Infant Testing and Follow-up Register to facilitate timely infant follow up. Columns/fields for infant HIV testing laboratory registers are included in “Appendix 5: Laboratory Activity Monitoring”.

**(2) Clinic-held medical charts.** Ideally, registers are complemented by clinic-held medical charts for each infant and each parent enrolled in care at the facility. The medical chart provides more detailed information on each patient encounter, including healthcare provider impressions and laboratory test reports. Where the clinic-held medical chart is electronic, it is referred to as an electronic health (or medical) record.

**(3) Electronic records.** In many countries, paper registers and charts have been replaced by electronic record systems/databases and lab information systems. The advantage of the electronic system is that multiple registers (PMTCT register, HIV-exposed infant register, DBS specimen tracking register, baby testing and follow-up register) can be combined into a single database or captured in a system of linked databases. Data from these linked databases can be set up to be automatically de-identified and/or aggregated into a separate analysis and dashboard platform that can be accessed by all agencies, searched, used to monitor and evaluate services, and used for research.

Where such a national database does not exist, potential programs for developing a sub-national database include Microsoft Access or Epi-Info (preferably not Excel, as this is not really a database programme and it is difficult to maintain data quality in Excel). The task of developing the database may be contracted to a local data management firm.

**Table 3: PEPFAR Monitoring, Evaluation and Results (MER) indicators**

<table>
<thead>
<tr>
<th>MER Indicator</th>
<th>Description</th>
<th>Reporting Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of pregnant women with known HIV status at antenatal care (ANC) (includes those who already knew their HIV status prior to ANC1)</td>
<td><strong>Numerator:</strong> Number of pregnant women with known HIV status at first antenatal care visit (ANC1) (includes those who already knew their HIV status prior to ANC1)  <strong>Denominator:</strong> Number of new ANC clients in reporting period</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Indicator</td>
<td>Description</td>
<td>Numerator</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
<td>-----------</td>
</tr>
<tr>
<td>HIV status prior to ANC</td>
<td>Disaggregates: known positive at entry, newly tested positive, new negatives, recent negative at entry</td>
<td></td>
</tr>
<tr>
<td>Percentage of HIV-positive pregnant women who received ART to reduce the risk of mother-to-child-transmission during pregnancy</td>
<td>Numerator: Number of HIV-positive pregnant women who received ART to reduce the risk of mother-to-child-transmission during pregnancy</td>
<td>Denominator: Number of new ANC clients in reporting period</td>
</tr>
<tr>
<td>Percentage of infants born to HIV-positive women who received a first virologic HIV test (sample collected) by 12 months of age</td>
<td>Numerator: Number of infants who had a first virologic HIV test (sample collected) by 12 months of age during the reporting period</td>
<td>Denominator: Number of new ANC clients in reporting period</td>
</tr>
<tr>
<td>Number of HIV-infected infants identified in the reporting period, whose diagnostic sample was collected by 12 months of age.</td>
<td>Numerator: Number of HIV-infected infants identified in the reporting period, whose diagnostic sample was collected by 12 months of age.</td>
<td>Denominator: N/A</td>
</tr>
<tr>
<td>Percentage of ART patients with a suppressed viral load (VL) result (&lt;1,000 copies/ml) documented in the medical or laboratory records/laboratory information systems (LIS) within the past 12 months</td>
<td>Numerator: Number of ART patients with suppressed VL results (&lt;1,000 copies/ml) documented in the medical or laboratory records/laboratory information systems (LIS) within the past 12 months</td>
<td>Denominator: Number of ART patients with a VL result documented in the medical or laboratory records/laboratory information systems (LIS) within the past 12 months.</td>
</tr>
<tr>
<td>Percentage of final outcomes among HIV exposed infants registered in a birth cohort</td>
<td>Numerator: Number of HIV-exposed infants with a documented outcome by 18 months of age disaggregated by outcome type</td>
<td>Denominator: Number of HIV-exposed infants who were born 24 months prior to the reporting period and registered in the birth cohort.</td>
</tr>
</tbody>
</table>
Disaggregates: HIV-infected, HIV-uninfected, HIV-final status unknown, died without status known

Indicators, programmatic
The PMTCT and infant HIV testing activities that need to be evaluated, to tell us whether we have achieved the programme goal, are usually set at a national level and based on programme, global and funding requirements. The indicators in Table 3 are the PEPFAR MER indicators relevant to infant testing developed and collected by PEPFAR implementing partners. Most countries will have additional indicators that are routinely monitored, including the Global AIDS Monitoring indicators developed by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and WHO (listed in Appendix 6).

Indicators, laboratory
Laboratory monitoring and evaluation for infant HIV testing may include the following indicators:

(1) High throughput testing, laboratory-based technologies. Laboratories may consider monitoring the following indicators:

- Total turnaround time: both laboratory and clinical aspects of turnaround time that determine the interval from sample collection to sharing of results with the client, including:
  - Time from sample collection to pickup for transport to laboratory
  - Time in transit from clinic to laboratory
  - Time from sample collection to arrival in laboratory
  - Time from arrival in laboratory to final test result
  - Time from test completion to receipt of result at clinical site*
  - Time from result at clinic site to sharing of results with the client/caregiver*
- Percent of DBS samples rejected by laboratory, by site (to direct re-training needs)
- Percent of samples with indeterminate result
- QA, External Quality Assurance (EQA), and Quality Control (QC) data including but not limited to:
  - Verification of equipment and assays prior to putting into use
  - Plot of external control results to monitor stability/reliability
  - Proficiency testing (PT) enrolment and results
- Supply stock outs, equipment failures, and other laboratory shutdowns—number of days unable to test and reasons for shutdowns should be tracked

* = not specifically a laboratory indicator, but does factor into turnaround time.

(2) PoC testing technologies. Sites conducting PoC testing will want to track the following indicators:

- Time from sample collection to post-test counselling session
- Percent of specimens that needed to be re-collected due to insufficient or incorrect sampling (to direct re-training needs)
- Percent of samples with invalid/indeterminate/ERROR result
- QA, EQA, and QC data including but not limited to:
  - Verification of equipment and assays prior to putting into use
- Plot of external control results to monitor stability/reliability
- PT enrolment and results

- Supply stock outs, equipment failures, and other shutdowns—number of days unable to test and reasons for shutdowns should be tracked on a calendar

(3) National-level laboratory indicators. Regional and national health authorities may collect information to report on the following national-level indicators:

- Number of sites performing infant virologic testing
- Number and type of infant testing platforms (conventional and PoC) at the sites
- Number of sites participating in PT programmes
- Number of sites that achieved acceptable passing criteria in PT programmes

An example of a national quarterly report, including some of the above measures, is included as Appendix 7.

Local level reporting and analysis
At the facility level, aggregate summaries of all indicators should be tallied on a monthly or quarterly basis and submitted to the local or subnational Programme Manager for review. Data on each of the core indicators provide information to monitor and evaluate HIV-exposed infant care and testing. This monitoring data will pinpoint which interventions have been implemented well and which need improvement. For example, if monitoring data indicates that 35% of HIV-exposed infants at Clinic X are started on cotrimoxazole prophylaxis within 2 months of birth and the national goal for this indicator is 90%, the local or subnational Programme Manager should prioritize this indicator for improvement. “Section 6: Ongoing Supervision and Quality Improvement (QI)” includes a detailed discussion on QA and QI using data from monitoring and evaluation.

Accurate and consistent data recording

The Programme Manager usually takes the lead to ensure that all healthcare providers are trained in the correct completion of monitoring tools as well as infant HIV testing-related forms (such as DBS cards and laboratory requisition forms). An important role of the Programme Manager is to ensure that the data used for monitoring and evaluation is recorded accurately, consistently, legibly, and in a timely manner every time an activity is conducted. The following checklist may be useful when reviewing for data quality at the site level.

Do healthcare providers responsible for recording client information in registers/databases or other forms:

- [ ] Understand the data to be recorded?
- [ ] Record the required data in the required format each time a service is provided?
- [ ] Fill out forms/registers completely (doing so might require noting when a service was not provided)?
- [ ] Record the data in the same way every time correctly following the key/using the same definition every time?
Regular data audits are critical for ensuring that data is of high quality. During routine data audits determine:

- Are registers filled out completely?
- Are the data valid/accurate?
- Are the data reliable (the same every time, consistency in format)?

The information from a monitoring system is only as useful as the quality of the information recorded in registers/databases, client records, and other forms used for monitoring.

**Programme Manager’s role**

The activities that are tracked as part of monitoring and evaluation efforts are usually determined at the country level, but the local/subnational programme manager has a key role in:

- Ensuring infant HIV testing activities are recorded accurately, consistently, legibly and in a timely manner every time and activity is conducted using the standard forms, registers/databases (for more on this, see text box above “Accurate and Consistent Data Recording”)
- Providing support to ensure facilities are collecting monitoring and evaluation data correctly
- Analysing and using monitoring information collated by staff
- Comparing monitoring information with objectives and targets and deciding if these objectives and targets have been met
- Leading a discussion on how to ensure objectives and targets are met
- Leading evaluation activities
- Supporting facilities to implement plans to achieve their objectives and targets
- Deciding whether there are additional activities that should be monitored or evaluated based on feedback from clients or staff or on monitoring or evaluation data.
3. Identification of HIV-exposed Infants

In most countries, the care of HIV-exposed infants is integrated with PMTCT services. With this approach, HIV-exposed infants are automatically identified as their mothers are known to be HIV-infected and enrolled in PMTCT programs.

The challenges with this system are (1) identifying infants not enrolled in PMTCT services, and (2) ensuring that these mothers and their infants are enrolled and retained in care and return to the PMTCT programme for infant testing.

To facilitate finding infants whose mother’s HIV infection was unknown in antenatal care (ANC) (or who did not attend ANC), WHO recommends the integration of infant HIV testing services into established services routinely utilized by infants and their families, including immunization, well-child, postnatal, nutrition, HIV specialty, and other clinics.

HIV testing in health facilities should be routine

HIV testing of all mothers, HIV-exposed children, children of unknown exposure status, and sick children should be routine (also referred to as “provider-initiated”). Parents and guardians of children who are tested need to be informed that testing is urgent as the medications used to treat HIV infection are life saving and will prevent early death if the child is found to be HIV-infected. In addition, if a child is sick, knowing the HIV status of the child will help the clinician to treat the child appropriately (for example, to give the correct medicines for diarrhoea or pneumonia).

In generalized epidemics, HIV testing should be routinely offered to infants, children, and adolescents with unknown HIV status in the following settings:

- Child health services, immunization clinics, under-5 clinics
- TB clinic
- Nutrition clinics
- Services for orphaned and vulnerable children (16)
- Any HIV service (e.g., PMTCT, ART) where parents or siblings are receiving care
- All inpatient wards, especially if the child is being hospitalized for an infection that may be HIV related

Strategies for identification of the HIV-exposed infant

The following strategies can be used throughout the MCH and other systems of care to ensure that all HIV-exposed infants are identified and followed in a timely manner.

- **Transfer of information about maternal HIV status from antenatal to follow-up care using the child health card.** Countries that have not yet updated their antenatal and child health cards and registers to include HIV and PMTCT information are encouraged to do so. With coordination between antenatal, delivery, postnatal, and child health services, information on maternal HIV status (the child’s HIV-exposure status) and maternal ART, can be easily transferred from the antenatal card to the child health card when it is issued. Facilities offering both antenatal and postnatal services should develop strategies for improving communication, cooperative case management and information transfer. Examples of HIV-related fields that can
be added to the child health card are in “Appendix 8: Sample PMTCT Page for Child Health Card”.

- **Routine screening of infants of unknown HIV-exposure status.** Mothers of unknown HIV status should be tested for HIV using RDT when they present for their own postnatal care or for their infant’s immunization visit to establish their HIV status and the HIV exposure status of the infant. In areas with well-developed PMTCT services this situation should be uncommon and should not place undue burden on facility staff. However, the definition of “unknown status” depends on the guidelines for frequency of retesting after a HIV-negative test result, so a larger proportion of women may need HIV testing in the first postpartum/immunization visit in settings where frequent retesting is recommended in national guidelines.
  
  - If HIV status/HIV-exposure status is not documented, then the mother should be asked when she was last tested for HIV.
  
  - If the mother previously tested HIV-positive, then she is considered to be HIV-infected. WHO recommends confirmatory testing before starting ART(16).
  
  - If the mother does not have documentation of recent testing, then routinely offer testing, using RDT, as per national guidelines.

- **If the mother is not available for testing or refuses testing**, provide infant testing using RDT:
  
  - An HIV-positive test result means:
    - Child under the age of 18 months: HIV-exposed
    - Child 18 months of age or older: HIV-infected
  
  - An HIV-negative test result means:
    - Infant under 4 months of age: not HIV-exposed
    - Child 4–18 months of age: HIV-exposure cannot be ruled out, infant may have cleared maternal antibody. If sick, the infant should be tested using NAT; otherwise test again at 18 months of age using a RDT.
    - Adult or child 18 months of age or older: HIV-uninfected, unless still breastfeeding, or breastfed within the past 3 months. Repeat RDT 3 months after cessation of breastfeeding.

NOTE: Children on ART should not be re-tested using RDT. An HIV-infected infant initiated on ART may subsequently test HIV-negative by RDT; this is especially common if ART is initiated at a very early age (before 12 weeks of age). This is because ART can stop the antibody response if initiated very early in life or the antibody response can wane over time with control of the virus (17).

If a sick infant or child, less than 18 months of age, tests HIV negative by RDT and if index of suspicion is high, conduct virologic testing. See Table 4, which is a summary of the use of RDT in HIV-exposed infants.
Table 4: Use of RDT for identification of HIV-exposed infants, based on age and breastfeeding practice

<table>
<thead>
<tr>
<th>Age group</th>
<th>Unknown HIV exposure status</th>
</tr>
</thead>
</table>
| 0–4 months | Test mother  
If mother is not available:  
- RDT in the child can reliably assess exposure |
| 5–18 months | Test mother  
If mother is not available:  
- A positive RDT establishes exposure. Infants with positive RDT should get NAT to confirm infection.  
- A negative RDT for the child does not fully rule out exposure. Perform NAT to assess HIV infection status in any sick child**  
- Infants with negative RDT who are still breastfeeding will need testing 3 months after cessation of breastfeeding  
- If sick or index of suspicion is high, conduct virologic testing. |
| >18 months |  
- Serological testing (including RDT) is recommended to assess HIV infection status unless breastfed within the last 3 months or still breastfed.  
- If still breastfed, RDT should be provided 3 months after cessation of breastfeeding. |

**Consider initiating ART for presumed HIV infection if there is high degree of suspicion while waiting for NAT results, especially if RDT positive.  
NAT = Nucleic acid testing, a virological test

Adapted from: WHO, 2018 (3).

Programme Manager’s role
It is the Programme Manager’s role to ensure that there are no barriers to the routine HIV testing of mothers, or where the mother is not available, infants/children to determine the HIV-exposure status of all infants and children, regardless of the healthcare setting. The Programme Manager is also expected to support and monitor systems for identification of HIV-exposed infants, both within and outside of the PMTCT programme.
4. Retention in Care

It is critical to retain HIV-exposed infants in care until final assessment of HIV status at 18 months or age or at least 3 months after cessation of breastfeeding (whichever is later). Retention in care is critical both to ensure that mother-infant pairs receive the care and treatment they need to prevent vertical transmission and for timely diagnosis and initiation of ART for HIV-infected infants. However, diagnosis and access to treatment is often delayed:

- Infant HIV testing: In 2018 only 54.9% of newborns exposed to HIV received an HIV test within the recommended first two months of life. Even fewer were retained in care and tested at 18 months of age or after the end of breastfeeding.
- Provision of ART: In 2018, over half (54%) of all children living with HIV were accessing treatment, far short of global targets.

It is important that Programme Managers understand the importance of retention in care and minimizing loss to follow up (LTFU). LTFU of mothers and/or infants can result in not meeting the UNAIDS 90-90-90/95-95-95 targets — if an infant is LTFU, s/he will not be tested. If an infant is not tested or fails to return for test results, s/he will not be linked to care. Additionally, it is critical to ensure that mothers enrolled in PMTCT programs are retained in care and virally suppressed on ART.

**UNAIDS 90-90-90 and 95-95-95 targets:**

- By 2020, 90% of all people living with HIV will know their HIV status.
- By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy.
- By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression.
- By 2030, 95% of all people living with HIV will know their HIV status.
- By 2030, 95% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy.
- By 2030, 95% of all people receiving antiretroviral therapy will have viral suppression.

For more information, see http://www.unaids.org/en/resources/documents/2014/JC2686_WAD2014report

**Initiatives to identify HIV-exposed infants who miss appointments/LTFU**

Given the rapid progression of disease in infants with HIV, the goal is to provide HIV virological testing to all HIV-exposed infants at 4–6 weeks of age and to ensure the results from virological testing are returned to families within 4 weeks of testing if the specimen is sent to an off-site laboratory for analysis. Of note, countries may have specific definitions for LTFU based on time since last visit or missed appointment; in this section, we generally use the term LTFU to refer to mothers/infants who have not returned to the clinic at the recommended intervals. There are a number of ways that patients LTFU can be monitored.

- Using antenatal/PMTCT registers to identify HIV-exposed infants who are not enrolled in care: If a woman identified as HIV-infected in antenatal care does not return for follow up
care and infant testing within 6 weeks of delivery, she should be traced and brought in for postnatal care (for herself) and to initiate the comprehensive package of care, including HIV testing, for her infant. To do this, MCH services need access to the antenatal and/or PMTCT registers.

- **Using appointment ledgers/database to track missed appointments/LTFU and give appointment reminders.** If electronic or paper appointment systems are used, then the appointment system should be reviewed each day and the patients (mothers and infants) who did not show marked for follow up the next day. Appointment registers have also been used to provide appointment reminders the day before the scheduled appointment in the form of calls or text messages to prevent missed appointments.

- **Using registers to identify infants initially enrolled in care who are then LTFU and miss testing visits:** Patients LTFU (i.e., patients who never showed for a routine follow up visit) can be identified using the register. For example, the HIV-exposed infant Cohort Register can be used to track virological testing in infants by analysing which rows have entries in the column entitled “Date of Initial PCR” and “Date of Repeat/confirmatory PCR” (see Appendix 4). Empty cells indicate that the corresponding child has not yet been tested. Looking back at date of delivery, one can calculate the infant’s age and discern if overdue for testing.

  Use the “PCR results, pos/neg/invalid” column to track whether or not results have been received. Use the “Date final results collected by guardian” column to identify infants whose guardians have not yet been post-test counselled. Infants who are overdue for any of these essential components can be identified (as the cells where the child’s row and the appropriate column meet will be empty) and then be tracked. Review of the register should take place weekly by an individual in the clinic who takes responsibility for this role and is given authority to identify the best mechanism to follow up all patients LTFU.

  Similarly, the DBS Specimen Tracking Register or Baby Testing and Follow-up Register can be used to identify missing specimens, missing results, or patients who have not turned up for essential services.

- **Tracing pharmacy refills:** A community-based ART cohort in Cape Town, South Africa uses the intelligent electronic pharmacy system to dispense ART (iDART for intelligent dispensing of ART) and generate lists of patients who have failed to pick-up medication(18). Such a system could be used to identify mothers who have not picked up ART and infants who have not accessed cotrimoxazole (HIV-infected and exposed infants) or ART (HIV-infected infants).
Kenya’s early infant diagnosis dashboard*

The Kenya national HIV programme has developed an EID Dashboard that aims to improve infant HIV testing outcomes, including timely reporting of infant HIV testing results nationally. The dashboard can be accessed to get test results for individual clients, information on turnaround time for specimens, and allows for analysis of trends over time by county and health facility. The Dashboard can also be used to assess facility performance such as number of tests submitted, number rejected, and testing trends, e.g., time from sample collection to receipt at the lab, time from receipt to testing, and time from testing to release of results both at the lab level and nationally.

The EID dashboard can be accessed by logging in either by facility, by county, or by implementing partner. Facility login allows healthcare workers to access the past and present results of individual clients. The results can be printed and emailed, or transmitted by short message service (SMS), to the health facility. There is also a plan to send results directly to the patient via SMS. *

There are several data visualization reports that can be generated automatically from the dashboard, broken down by county, e.g., trends in initial NAT results, EID outcomes by age, entry point, maternal PMTCT regimen, and infant prophylaxis (see Appendix 7).

*https://eid.nascop.org/

Tracking caregivers to provide test results

Each district or site needs a plan for following up caregivers who do not return in a timely manner to receive their child’s results. HIV-positive infants should be first priority for these efforts, as they are at risk of dying while awaiting results. All efforts should be made to obtain and clearly document physical and telephone contact information for the family at time of enrolment, and staff should be assigned to the task of finding lost infants. This could be a counsellor, nurse, social worker, or lay provider. In most cases, this staff person will need phone credit and/or transportation. In sites with successful PMTCT programmes, the number of HIV-infected children who need to be traced will be small.

- Contact the caregiver as soon as you receive an HIV-positive result from the laboratory and ask them to come to the clinic immediately for the post-test session, preferably that working day. **In other words, do not wait for a scheduled result return appointment to give a caregiver an HIV-positive result!!** Treat an HIV-positive result on an infant as an emergency. Initial contact may be made by phone or text, where available, or by home visit should the parent not have a phone. Where contact is made by home visit and by a staff qualified to provide post-test counselling, consider conducting the post-test session at home and then escorting the caregiver and infant directly to the HIV care and treatment site to initiate ART.

- If a caregiver does not return for their child’s result at the scheduled appointment and that test result is negative, follow up to ensure the caregiver is not only informed of the test result but also to ensure that they remain in care.
**Linkage to care and treatment for HIV-infected infants**
Each infant testing site needs a plan for ensuring infants and children testing HIV-positive are promptly provided with HIV-related care and treatment. Where ART is provided on site, the goal should be to enrol the child in care on the same day that post-test counselling is provided. Where care is provided off-site, by referral, the goal should be to accompany the child and caregiver to the care and treatment site on the same day that the test result was provided, or where that is not possible, within a few days of diagnosis. More on linkages to care can be found in “Section 10: Linkage of HIV-infected Infants to ART”.

**Optimizing retention**
Strategies to optimize retention of infants and children in HIV programs must address key barriers to retention, including: individual-level barriers, partner/community barriers, and health systems barriers. These barriers as well as potential initiatives to address them are discussed in Table 5.

**Table 5: Barriers to access and retention in PMTCT and infant HIV testing services and possible interventions**

<table>
<thead>
<tr>
<th>Category</th>
<th>Barrier</th>
<th>Possible interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>• Illness: retention is especially challenging for younger, sicker HIV-infected or exposed children.</td>
<td>• Outreach services</td>
</tr>
<tr>
<td></td>
<td>• Denial/shock (following results)/depression</td>
<td>• Mobile phone reminders</td>
</tr>
<tr>
<td></td>
<td>• Poor knowledge of HIV/MTCT/ARVs</td>
<td>• Home care</td>
</tr>
<tr>
<td></td>
<td>• Unaware of the importance of ANC and when ANC should start</td>
<td>• Strengthened supportive counselling and educational strategies</td>
</tr>
<tr>
<td></td>
<td>• Fear of being HIV-positive/death/ARVs</td>
<td>• Careful management and advice for women initiating ART, including education on side-effects</td>
</tr>
<tr>
<td></td>
<td>• Stigma and fear of disclosures</td>
<td>• Peer-support for other HIV-positive individuals</td>
</tr>
<tr>
<td></td>
<td>• Sudden/unclear/early/night-time onset of labour</td>
<td>• Where pamphlets are used, ensure illiteracy and fear of disclosure are considered</td>
</tr>
<tr>
<td></td>
<td>• Lost/sold/stolen/forgetting/ran out of tablets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Difficulties administering infant treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Caregiver decisions about their child’s treatment can be influenced by transport costs, food availability, time constraints, perceptions that the child is healthy, perceived stigma, religious beliefs, lack of male partner support, lack of knowledge about benefits of care and treatment.</td>
<td></td>
</tr>
<tr>
<td>Partner and community</td>
<td>• Disclosure issues/fear of disclosure</td>
<td>• Engage men in programme to improve communication, disclosure, and support</td>
</tr>
<tr>
<td></td>
<td>• Discrimination by partners, community</td>
<td>• Expand PMTCT/infant HIV testing interventions to include other family members (particularly in counselling)</td>
</tr>
<tr>
<td></td>
<td>• Relationship strains/violence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lack of partner support</td>
<td></td>
</tr>
</tbody>
</table>
**Health-systems**

- Lack of community support
- Fear of someone finding/seeing pills
- Cultural traditions, including preferences for traditional healers, traditional birth attendants, and home births
- Strong role of elders and associated beliefs

- Community-driven participatory communication strategies
- Community education about PMTCT and sensitization to HIV, especially involving elders and community leaders
- Involvement of HIV-positive individuals in tackling stigma
- Peer-support and counselling

- Health-systems

<table>
<thead>
<tr>
<th>Prevention Barrier</th>
<th>Prevention Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of community support</td>
<td>Community-driven participatory communication strategies</td>
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</tr>
<tr>
<td>Strong role of elders and associated beliefs</td>
<td>Peer-support and counselling</td>
</tr>
</tbody>
</table>

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Adapted from: Gourlay A et al, 2013. (19) and Phelps BR et al, 2013. (20)
**Programme Manager’s role**

It is the Programme Manager’s role to ensure that health facilities have in place the systems to track LTFU and, as importantly, actually undertake the efforts needed to identify patients who miss appointments or drop out of care. It is also the role of the Programme Manager to ensure that patients diagnosed with HIV infection have minimal barriers to attending the care and treatment site. The Programme Manager will need to visit the health facilities in his/her jurisdiction to assess systems for LTFU and track periodic monitoring reports to identify sites with high LTFU. Some Programme Manager will find themselves having to negotiate on behalf of their health facilities to ensure adequate funding of systems and staffing to minimize LTFU.
5. Healthcare Provider Selection and Training

Healthcare provider licensure
National infant HIV testing programmes usually provide guidance on who may conduct which duties related to the implementation of the comprehensive package of care for HIV-exposed infants (see pages 12–13), including HIV testing. National guidelines and professional organizations typically outline the educational and practical requirements of each cadre of healthcare provider, whether nursing, medical, or laboratory. It is the duty of each clinic to ensure that the staff under their employment are fully licensed upon hire and retain that licensure as per the regulations of their respective professional bodies.

Training for infant HIV testing
Healthcare providers as well as lay providers may be trained to offer the comprehensive package of care for HIV-exposed infants, including pre- and post-test counselling; the collection of blood specimens; drying and packing of specimens; completion of laboratory requisition forms, other documentation, and registers; and safe disposal of biohazardous materials. With support and supervision, lay providers can be trained to offer testing and counselling services as well as accompanying clients to treatment and care services, and undertaking outreach to clients who have missed an appointment. Sites with large numbers of HIV-exposed infants may want to recruit and train additional lay or healthcare provider staff to scale-up infant HIV testing services.

Infant HIV testing training curriculum
A curriculum for staff training is included as Book 2, Infant HIV Testing Implementation Guide, Training Curriculum for Healthcare Providers. This curriculum is designed as a 5-day course: 3.5 days in the classroom and 1.5 days in a clinic-based practicum to practise the skills learned in the classroom setting. The practicum outlined in this curriculum is competency-based, guided by experienced preceptors, and concludes with end-of-day debriefings.

Training on PoC testing
The HIV Point-of-Care Diagnostics Toolkit contains practical tools and guidance to support countries as they introduce PoC HIV technologies into existing national diagnostic networks and laboratory systems. The document Guidance for Site Enrollment provides a summary of key steps for preparing and training sites to provide PoC testing. This Toolkit can be accessed at: http://childrenandaids.org/poc-toolkit-page
Task sharing and lay providers
Many countries continue to face shortages of trained healthcare providers. Task sharing is a pragmatic response to health workforce shortages. In their 2015 and 2016 guidelines, WHO recognized the importance of task sharing with lay providers to support implementation of infant HIV testing interventions. WHO recommends use of lay providers to perform a range of clinical services including HIV testing, education, counselling, referrals, adherence assessment and support, peer navigators, and community outreach(16).

Services led by trained lay providers, including peer-based interventions, can be a welcome and thus important means of delivering services, providing information and teaching skills that promote safer behaviours. Beyond providing services, lay workers who are their clients’ peers can act as role models and offer non-judgemental and respectful support that can help reduce stigma, facilitate access to services, and improve service uptake.

Where lay providers are engaged, clinics must also establish a system for managing and supporting lay providers. The individual tasked with managing lay providers must be not only trained to do so in a way that is supportive as well as educational, but also relieved of other duties so that they have enough time to support and guide the individuals they manage. Task sharing should not be seen as a means to save resources but rather one potentially valuable tool to improve access, coverage, and quality of services.

As an example of country guidelines, the Republic of Kenya Ministry of Health developed “Task Sharing Policy Guidelines, 2017-2030” to enable more effective health workforce utilization to increase service provision and improve quality of care. These guidelines provide guidance on training and education by cadre as well as task sharing by cadre and level. The guidelines can be found at https://www.hesma.or.ke/wp-content/uploads/2017/02/Task-Sharing-Guideline-2017.pdf.

Identifying qualified trainers
It is important to hire and equip training teams to support not only scale up of infant HIV testing services and comprehensive care for HIV-exposed infants but also ongoing refresher training and new staff training needs. Ideal training teams should have expertise in both the clinical care of HIV-exposed and HIV-infected infants as well as knowledge of DBS procedures and laboratory testing. They need to be trained (training of trainers) on the national curriculum and they need to be provided with the materials they need to train (laptop computers, projector if available, copies of national guidelines documents, copies of national training curriculum participant manuals, other materials for training), budget for supplies, rental of training venue, food for trainees/trainee per diem (as indicated), and transportation.

Supportive supervision: Training should be complemented with supportive supervision. Training teams that include an HIV clinician, monitoring and evaluation staff, and laboratorian can provide
quarterly, semi-annual, or as needed supportive supervision visits. Supportive supervision is discussed further in the next section.

Additional staffing considerations

Clinic staffing

- **Train sufficient clinic staff so that infant HIV testing services can be offered at any time:** Consider training all staff that see children—whether for routine immunizations or for sick visits—to conduct infant HIV testing interventions. In settings where DBS are sent to a laboratory for NAT (versus PoC testing), infant testing should be made available whenever the health facility is open, because DBS cards do not require immediate transport to a laboratory. There is no need for special testing days, since DBS obtained even on a Friday afternoon can wait until the following week to be sent to the laboratory. However, clinical staff must keep in mind that DBS need to be dried and packaged within 24 hours of collection and should be sent to the laboratory within one week of collection to maintain specimen integrity and minimize turnaround time.

- **Training on PoC technologies:** With PoC technology, a qualified laboratorian is not required but the healthcare provider must be adequately trained. To ensure uninterrupted service provision, it is important that at least two, but preferably all healthcare staff, are trained and deemed competent in the operation of PoC technologies in their clinical setting. However, given the amount of time that PoC technologies will require from clinical staff, when introducing PoC testing, Programme Managers and clinical staff may need to consider how to cover clinical workload given this new role.

- **Follow up of lost test results and caregivers LTFU:** Where DBS specimens are sent to a laboratory (versus PoC testing), clinics should assign a staff member to review testing registers each week and contact (via phone, fax, e-mail, text, or in-person visit) the laboratory to locate results that have not been returned to the clinic within 28 days. Someone in the clinic will also need to be responsible for following up caregivers who have not returned for their child’s test results within 3 days of results receipt by the clinic. The goal of infant HIV testing is to identify infants with HIV-infection early so that they can initiate ART before they get sick, this is not possible without the return of test results to the clinic and then to the caregiver in a timely manner.

Laboratory staffing

- **High throughput technologies/laboratory-based NAT:** High throughput technologies require fully trained laboratory technicians. These technicians will need to be trained on the specific technology to which they will be assigned.

Programme Manager’s role

The Programme Manager will likely be involved in overseeing the recruitment and training of qualified and licensed/certified staff and ensuring that each clinic maintains a system for tracking the licensure of the professionals in their hire and that all staff meet licensing requirements for their cadre.

S/he will likely be tasked with planning training, engaging trainers, organizing the practicum for training participants, ensuring that all staff involved in infant HIV testing services are trained, and then monitoring and evaluating training. The Programme Manager is also likely to be involved in overseeing the recruitment, training, management, and supervision of lay providers.
The following document, although targeted to national Programme Managers, may be provide helpful guidance around human resources for health:


6. **Ongoing Supervision and Quality Improvement (QI)**

**Supportive supervision**
Supportive supervision complements training by providing one-to-one, long-term support for staff to perform tasks within their roles to national standards. Supportive supervision aims to:

- Obtain valuable information on programme functioning and quality.
- Improve healthcare provider performance by offering one-to-one support to address an identified deficiency.
- Acknowledge good practices by providing positive feedback and noting contributions to the success of the programme.
- Involve both supervisors and healthcare providers to improve service provision; it is not the sole responsibility of the Programme Manager. Healthcare providers can support each other by mentoring their peers. For example, the healthcare provider skilled at taking DBS specimens might mentor peers who are just learning this skill. Another healthcare provider who is experienced in completing clinic registers can show others how to ensure all columns are filled in correctly.
- Facilitate on-site, participatory problem solving. Healthcare providers should be encouraged to become comfortable actively participating with their supervisors to address weaknesses. QI is most effective when the focus is on providing guidance and mentorship, as well as group problem solving techniques, to assist healthcare providers to correct problems and overcome barriers to a high-quality programme.
- Assure the programme is successful in meeting the needs of HIV-exposed and HIV-infected children and their families.
- Motivate staff.

Supportive supervision should be established as quickly as possible to prevent poor practices from becoming routine.
Motivate staff during supportive supervision by:
- Praising and recognizing healthcare providers for work that is done well.
- Involving healthcare providers in the planning process—encourage healthcare providers to set targets and develop performance monitoring indicators.
- Soliciting and acting on feedback received from healthcare providers.

Table 6: Comparison of traditional and supportive supervision

<table>
<thead>
<tr>
<th>Action</th>
<th>Traditional supervision</th>
<th>Supportive supervision</th>
</tr>
</thead>
</table>
| What happens during supervision encounters | • Inspection of facility  
• Review of records and supplies  
• Supervisor makes most of the decisions  
• Reactive problem solving by supervisor  
• Little feedback or discussion of supervisor observations | • Observation of performance and comparison to standards  
• Provision of corrective and supportive feedback  
• Discussion with clients  
• Provision of technical updates and guidelines  
• On-site training  
• Use of data and client input to identify opportunities for improvement  
• Joint problem solving |
The WHO Global Strategy on people-centred and integrated health services

There are many different aspects involved in the successful provision of HIV-exposed infant care. In order to attract and retain clients, the staff at a healthcare facility have to be more than technically competent; their services must also be accessible and people-centred.

The WHO global strategy on people-centred and integrated health services (see definitions in box below) represents a fundamental shift in the way health services should be funded, managed, and delivered (22). Without a people-centred and integrated health services approach, healthcare will become increasingly fragmented, inefficient and unsustainable. The strategy proposes that all people have access to health services provided in a way that responds to their needs and that are equitable, safe, effective, efficient, timely, and of an acceptable quality.

Within the context of HIV care service delivery, people-centred care includes (22):

- Building healthcare providers’ skills for effective communication with people;
- Providing information and supporting people to make informed decisions and for their active engagement in their own care and self-management;
- Offering a patient appointment system and acceptable frequency of facility visits;
- Avoiding long health facility waiting times during clinical consultations, medication pick-up, or laboratory services;
- Coordinating care when people require multiple services (e.g., TB and HIV treatment, family-centred care); and
- Providing comprehensive integrated services, as appropriate and relevant.

**People-centred and integrated**

**People-centred health services** involve an approach to care that consciously adopts the perspectives of individuals, families, and communities and sees them as participants as well as beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways. People-centred care requires that people have the education and support they need to make decisions and participate in their own care. It is organized around the health needs and expectations of people rather than diseases.

**Integrated health services** are health services that are managed and delivered in a way that ensures that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation, and palliative care services at the different levels and sites of care within the health system and according to their needs, throughout their whole life.
Quality improvement (QI)

Whether or not the Programme Manager directly manages healthcare staff, s/he has responsibility for ensuring that clinic staff are providing quality services that conform to national guidelines and are accessible and people-centred. The Programme Manager is responsible for more than assuring the quality of services, s/he is responsible for QI, supporting staff to improve services, i.e., supporting healthcare providers to identify problems so that they can be corrected, thereby improving services for infants and their families. QI includes the systematic and continuous actions that lead to measurable improvement in services and, as a result, the health status of targeted patient groups. Whereas QA is the maintenance of a desired level of quality, QI is the improvement in quality. In this Section, discussion centres on QI rather than QA.

Supportive supervision and QI activities are closely related. Supportive supervision requires the Programme Manager or her representative to work with staff to establish goals, monitor performance, identify and correct problems, and proactively improve the quality of services through training, one-to-one support, mentoring, and coaching. Key issues to be addressed through supportive supervision are often identified during QI activities.

Methods to assess quality

It is often necessary to use a variety of methods to assess programme quality. Standard monitoring tools, such as patient charts and registers/databases, capture only a fraction of the services provided and offer little information on the quality of those services. QI activities might examine and evaluate:

- The quality, accessibility, and people-centredness of services
- Compliance with national guidelines, SOPs, and protocols for HIV care and treatment
- The adequacy of space and the attention to privacy and confidentiality
- Linkages to ongoing support and community-based services

Figure 3 illustrates the PDSA cycle, which includes 4 steps: developing a Plan, carrying out the plan (Do), observing and learning from the consequences through monitoring and evaluation (Study), and determining what modification should be made by using the analysis to implement an improved intervention to better meet targets (Act). The following is an example:

- **What is the problem (Study)?** Using the example from “Section 2: Monitoring and Evaluation Systems” (if monitoring data indicates that 35% of HIV-exposed infants at Clinic X are started on cotrimoxazole prophylaxis within 2 months of birth and the national goal for this indicator is 90%), why do you think only 35% of infants seen at Clinic X are started on cotrimoxazole? Has there been a stock out of this medication? Are the healthcare providers aware of its life-saving benefits? What are healthcare providers saying to caregivers about this medicine?

- **What modifications need to be made to address the problem (Act)?** This will depend on findings from the study phase (above).
• Develop a Plan that addresses the identified problem and follows the modifications that have been agreed upon. Who will address the issue, by when, and using what funding and other resources (if needed)?

• Carry out the plan (Do). How will we know if the revised initiative is working (Study)? What improvement do we expect to see and by when? Will we consider the modifications successful if our cotrimoxazole initiation increases to 40%? 65%? 80%? When do we expect to reach the national target of 90%?

Figure 3: Monitoring and evaluation as a continuous process: PDSA cycle
Cameroon’s quality improvement collaborative

The issue: In 2012 a Cameroon Ministry of Health (MOH) survey found that due to programmatic barriers, such as workload, staff training, availability of test kits, and other service delivery challenges:

- Only 12% of HIV-exposed infants were tested for HIV by the recommended 6 weeks of age
- Median turnaround time for infant virological testing was 3–4 months, far longer than the national standard

Solution: Between October 2015 and June 2017, ICAP at Columbia University, the MOH, the U.S. Health Resources and Services Administration (HRSA), and CDC-Cameroon worked together to design and implement a Quality Improvement Collaborative (QIC) to drive improvements in infant HIV testing and reduce testing turnaround time at 17 health facilities in the Centre and Littoral Regions.

How it was accomplished: The first step was to meet with key stakeholders to agree on a shared aim statement, indicators, and standard operating procedures for data collection and reporting. The dual aims were to:

- Improve infant HIV testing coverage to more than 50% of HIV-exposed infants (this was later amended to at least 90%)
- Reduce the average infant HIV testing turnaround time to less than 42 days (this was later amended to an average turnaround time of 2 weeks or less)

The second step was training of healthcare workers in QI methods along with initiation of monthly supportive supervision visits to each participating health facility, and quarterly learning sessions when teams from all of the health facilities convened to compare progress and experiences.

Health facility activities: Over the course of the QIC, teams worked to identify and prioritize interventions; conduct rapid tests of change using the Plan-Do-Study-Act (PDSA) cycle* methodology; collect facility-level data on a monthly basis using District Health Information System; and analyse progress using standardized run charts.

Results: The QI teams conducted 146 PDSA cycles and identified 30 successful change interventions. Outcomes:

- 16 of the 17 sites reached the HIV testing coverage target of >50%; on average this took 2.6 months to achieve
- All of the 17 sites reached and sustained the turnaround time target of <42 days
- These improvements triggered the development of more aggressive targets
- The improvements were sustained over time

* The PDSA cycle refers to the process of testing a change (or new initiative) by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act).

For more information see CDC, HRSA, PEPFAR, Cameroun Ministère de la Santé Publique, ICAP. Cameroon Early Infant Diagnosis Quality Improvement Collaborative, https://aidsfree.usaid.gov/sites/default/files/aidsfree.usaid.gov/sites/default/files/events/presentations/2018.1.18_eid-cameroon_0.pdf
QI at a day-to-day level
QI should be a routine part of the normal functioning of health facilities. QI incorporates procedures in which all staff, not just supervisors and Programme Managers, should be involved. QI is different from monitoring and evaluation. Monitoring can tell us how many infants received cotrimoxazole last month. Whereas QI can tell us whether the caregivers of those infants were satisfied with the services they received, whether they were provided with sufficient education, timely refills, and appropriate adherence counselling. QI information can provide insight on why we are or are not achieving targets (as reflected in monitoring data). On a day-to-day clinical level, for example, QI/QA helps to ensure:

- Patient flow: smooth, efficient, attentive to the needs of families
- Compliance with national guidelines, SOPs and protocols, including:
  - Identification of HIV-exposed children
  - Provision of comprehensive care for HIV-exposed infants
  - Content of pre-test information and post-test counselling
  - Procedures related to confidentiality
  - HIV testing procedures following algorithms based on the child’s age
  - Logistics management: supplies are adequate, not out of date, secure, forecasts are accurate
- Consistent use of universal precautions
- Proper collection and accurate interpretation of RDTs
- Proper collection of DBS specimens for NAT
- Tracking and follow up of NAT results
- Physical space: adequacy of space and attention to privacy
- Linkages to care and treatment
  - Provision of referrals and linkages to HIV care and treatment for the mother, child, and other family members as needed
  - Responsiveness to the priority needs expressed by the family
  - Tracking, follow up and documentation of missed appointments
  - Meeting national standards for ART

QI activities are most effective when the focus is on improving practice by providing guidance and mentorship, as well as group problem solving techniques.

Assessing quality
It is important to analyse services from a number of perspectives. For example, if only forms, client charts and registers were used to assess quality, there would be no information on the quality of the post-test counselling sessions, whether services were offered in private, and whether the healthcare provider treated the patient with respect. QA activities may include, for example:

- Regularly auditing standards of care and standards of procedure in comparison to national standards.
- Direct observation of procedures such as DBS blood sample collection, the pre-test session, the post-test session, HIV-antibody testing of a blood specimen, interpretation of HIV test results, and correct storage, packing, and shipping of DBS specimens.
- Periodic assessments of the client-friendliness of services (see “The WHO Global Strategy on People-centred and Integrated Health Services” earlier in this Section). Periodic reviews of
supply chain management to determine if supply forecasts are accurate: Are there too few supplies on hand and frequent stock outs? Are too many supplies ordered so that HIV test kits are frequently discarded because they are out of date?

- Interviews with staff indirectly or directly involved in infant HIV testing services to obtain feedback on specific indicators. A case conference format may be used as a forum to highlight current challenges, systems that are working and those that need improvement and provide a forum for proposing solutions.

- Individual interviews or focus groups with caregivers who receive care and treatment services at the clinic. Do caregivers feel that adequate information and support was provided in the counselling sessions? Were they clear about what was expected of them, e.g., how and when to follow up? Was their privacy respected?

- Client satisfaction surveys, which are typically given to clients as they complete their clinical visit, are a mechanism for clients to give their opinions about the services they received without fear that their honest feedback might affect their care. Client satisfaction surveys are typically administered either to all clients or to a random selection of clients for 1 to 2 weeks, 1 to 4 times a year.

- Evaluation of physical space, client flow, and time concerns through observation and staff and client/caregiver interviews.

- Meeting with representatives of services where clients are referred. Asking them about client needs, gaps in services, and feedback they may have received from caregivers of HIV-exposed infants regarding the facility’s services.

**QI findings and next steps**

Findings of a QI assessment need to be shared with in a timely manner with all staff. Findings are usually shared in a special team meeting that, ideally, includes the QI team, clinical staff, managers, and community representatives, such as community leaders, peer advocates, clients, or representatives from the Community Advisory Board. When facilitating these meetings, ensure staff are congratulated for QI findings that reflect positively on their work.

Outline key findings, one-by-one, that are short of standard. Involve staff in a discussion about each finding, discuss why this finding might fall below standard and what they can do to address this. Develop an action plan that lists:

- Key findings
- Recommendations
- Action steps
- Who is responsible for each action step and by when (date); these action steps should be integrated into routine staff performance reviews and annual salary increases (where applicable)
- When and how the changes will be evaluated

Reconvene the group biweekly or monthly, as needed to discuss new QI findings and to revisit the action plan developed at previous meeting(s) to evaluate progress and make further changes, if necessary.

**How often should QI be conducted?**

During initial implementation, daily or weekly QI activities allow for immediate follow up aimed at correcting problems that have been identified. As services become established, reviews should
become a formal part of programme monitoring activities at designated intervals (monthly progressing to quarterly reviews). For example, standards of care could be measured on a quarterly basis, but it might be sufficient to conduct client satisfaction surveys annually. Although Programme Managers have the ultimate responsibility for QI, QI-related activities should be shared among all members of the team.

It is important to establish a time for multidisciplinary team members and managers to discuss QI findings and issues, and to jointly come up with ideas and solutions for QI. This may be accomplished as part of routine, monthly multidisciplinary team meetings or through quarterly meetings dedicated to QI review.

Service quality checklist
See “Appendix 10: Supervision Checklist for Staff and Programme Managers.” This form is a resource for Programme Managers, supervisors, and healthcare providers involved in infant HIV testing services:

- To assist them in understanding what is expected.
- As a guide when mentoring, training, or otherwise supporting staff members.
- As a guide to ensure that guidelines and procedures are followed.
- The checklist can also be used to set goals and expectations, improve worker performance, and facilitate participatory problem solving.

The checklist includes questions that pertain to a variety of healthcare provider roles—including counsellors, data management staff and laboratory personnel—that can be answered only after direct observation of the employee in that role. In addition to evaluating proficiency, direct observation also provides supervisors with opportunity to assess staff attitude, particularly attitude towards clients and work.

Site Improvement Through Monitoring System (SIMS)
PEPFAR’s Site Improvement Through Monitoring System (SIMS) can be used as either an internal (conducted by site staff) or external (an audit conducted by staff not employed by the agency but rather by the funding agency) tool for assessing service quality. SIMS was developed for PEPFAR-funded providers, but can be used by non-PEPFAR providers as well. The goal of the SIMS is to increase the impact of PEPFAR programs through standardized monitoring of the quality of PEPFAR support at the site level (e.g., health facility; ward, district, etc.), focusing on key programme area elements.

SIMS aims to systematize and broaden ongoing site monitoring processes and improve documentation of this oversight; this is accomplished through administration of standard tools that assess adherence to PEPFAR standards of care and service delivery(23). The site assessment tool for PMTCT and paediatric care and treatment, is included as “Appendix 11: PEPFAR Site Improvement Through Monitoring System, Tool for PMTCT and Paediatric Care and Treatment”.

Programme Manager’s role
The Programme Manager is likely to be responsible for setting up supportive supervision systems in the health facilities for which s/he is responsible, for ensuring supportive supervision takes place in line with need and QI findings and that it occurs on a periodic basis as agreed with site staff. The
Programme Manager may want to use the tools in the appendices of this Guide to structure the supportive supervision sessions (see Appendices 12 and 13).

The Programme Manager may also want to set up systems to ensure that services in the health facilities under her/his watch provide people-centred care. It is possible that s/he may want to provide site managers with the supportive supervision that they need to lead the development of people-centred care, as people-centred care may be a unique concept.

As importantly, the Programme Manager will have a key role in implementing nationally-designed QI systems. S/he will also have a role in working with site managers to address deficiencies identified during QI activities by developing action plans with timelines for each objective in the action plan. The Programme Manager will be key in supporting the implementation of an action plan through practical support as well as identification of funding should a budget be required to address QI findings.
7. Laboratory Practices

Background for the Programme Manager
Given the Programme Manager’s overview of the entire spectrum of care, including laboratory, the following is an overview of infant HIV testing technologies as background.

Standard serologic tests such as the enzyme-linked immunosorbent assay (also referred to as ELISA) and RDT cannot differentiate transplacentally-acquired maternal antibodies from those of an infected infant and cannot make a definitive diagnosis of HIV in infants and children less than 18 months of age. Definitive diagnosis of HIV in infants less than 18 months of age requires the use of a laboratory or laboratory-developed methods to detect viral nucleic acids or proteins of the actual human immunodeficiency virus. In a young infant, HIV infection status can only be determined by such virologic tests.

Virologic testing
HIV infection in children under 18 months of age can be definitively diagnosed only with virological testing using NAT technologies. NAT detects viral nucleic acid (i.e., viral RNA, viral DNA or both) using a molecular amplification technique. Different manufacturers use different techniques. One of these techniques is a process called a polymerase chain reaction or PCR.

Qualitative HIV-1 PCR is a NAT procedure that detects the presence (but not the level) of HIV nucleic acid(s). This includes RNA and pro-viral DNA, a form of the HIV-1 genome produced by the integration of viral DNA into host peripheral blood mononuclear cell DNA. This NAT procedure is highly sensitive and specific even at birth, reaching near 100% sensitivity and specificity after the age of 4–6 weeks. NAT works well on DBS samples, which contributes to its considerable uptake in resource-limited settings. DBS, obtained from pricking the heel, toe, or finger of an infant with a lancet, are easy to collect from infants, are stable at room temperature, and are easy to transport to central laboratories making expanded access into peri-urban and rural settings possible. A recent study (24) concluded that there was no substantial difference in the use of fresh whole blood, plasma, or DBS samples in infant HIV testing.

Quantitative PCR testing: The procedure used to monitor disease progression or response to ART is VL testing, which tests the level of virus. VL testing can be conducted on either plasma or DBS.

Technologies available
Infant HIV diagnosis can be conducted on high throughput or PoC/near PoC instruments. There are a number of analysers that are validated for high throughput and PoC HIV infant testing. The analysers listed below have CE-IVD (Conformité Européene-In-Vitro Diagnostic) marking, meets WHO prequalification requirements, and/or FDA (US Food and Drug Administration) approval and are available in resource-limited settings.

High throughput technologies
High throughput HIV-1 assays for infant HIV testing must be performed on laboratory-based instruments and include:
- Roche (Roche Molecular Diagnostics COBAS® HIV-1 Qualitative Test), total nucleic acid (TNA) PCR technologies
- Abbott (Abbott RealTime Qualitative HIV-1 Test), TNA PCR technologies,
- BioMerieux (NucliSENS EasyQ HIV-1 V2.0), tests RNA only
- Aptima (APTIMA® HIV-1 RNA Qualitative Assay), tests RNA only. This analyser is not yet on the WHO prequalification list, but it is FDA approved.

**PoC and near-PoC technologies**

Point of care (PoC) virological testing using NAT technologies for infant HIV diagnosis (which for these purposes includes near point of care) is becoming widely available and can potentially play an important role in achieving UNAIDS targets(25). Two NAT PoC and near-PoC virological testing procedures have earned the CE-IVD Marking(26) and WHO prequalification:

- Alere™ q HIV-1/2 Detect (made by Abbott)
- Xpert® HIV-1 Qual Assay (made by Cepheid AB).

These technologies can be used to diagnose infants at the PoC (or near to the PoC) in as little as an hour. Both products are being studied in some countries with a high burden of HIV to determine how and where they should be used. WHO prequalification gives United Nations agencies and countries a guarantee of the test’s quality, safety and performance, and the confidence to buy and utilize them. Both tests use disposable cartridges that are pre-loaded with the chemicals needed to identify HIV in a blood sample. That means they are faster, smaller, and easier to manage than other tests that require the type of infrastructure and technical training that is typically only found in central laboratories.

Further considerations of benefits and challenges of introducing PoC and near-POC technologies for infant HIV testing are included in the HIV Point-of-Care Diagnostics Toolkit, available at: [http://childrenandaids.org/poc-toolkit-page](http://childrenandaids.org/poc-toolkit-page)

**Alere™ q HIV-1/2 Detect:** blood is collected by heel/toe or fingerstick into a sample capillary in a testing cartridge. The provider may also collect a blood sample using an EDTA (ethylenediamine tetraacetic acid) tube and then, using a pipette, transfer a few drops of blood (25 µL) from the EDTA tube into the sample capillary in the testing cartridge. The cartridge must be processed immediately(27). Plasma (25 µL) processed from blood collected in an EDTA tube may also be used for this assay. The mPima platform is portable and can run on a battery for up to eight hours, making it more suitable for use in remote and rural areas where there is no laboratory infrastructure and often few skilled health workers.

**Cepheid AB Xpert® HIV-1 Qual Assay:** blood is collected from the patient using heel/toe, fingerstick or venipuncture in a sterile tube using EDTA (lavender top) as the anticoagulant. A minimum of 100 µL of whole blood is then added to the testing cartridge. The test must be started within 30 minutes of adding blood to the cartridge. This technology can also be used on DBS(27). The Xpert® test runs on the same technology that is already used to diagnose TB. To test for HIV, it merely requires a change of cartridge, making it a cost-effective platform that can be used to test for multiple diseases. Xpert is not portable and is considered a “near PoC” device; it needs a continuous power supply and other infrastructure needed by high-throughput platforms.
(temperature control for operation, reduced dust, a computer and printer for results) but reduced maintenance needs and less training requirements.

Both procedures can be set-up and used either in the clinical setting or in a laboratory. Both give accurate results in 90 minutes or less and both use whole blood samples (Xpert® can also use DBS samples and Alere™ q HIV-1/2 Detect can also use plasma)(28).

Other technologies include the following:

- **Ultrasensitive (Us) p24 antigen-based (Ag) testing**: Us p24 Ag testing performs almost as well as the NAT for diagnosis of HIV in infants. The p24 Ag test has the advantage of being less complex and less costly than the NAT; it can be conducted in laboratory settings that can perform enzyme immunoassay testing (i.e., district and hospital laboratories as well as national reference laboratories). It can be conducted on plasma or DBS samples. The disadvantage of the p24 Ag is that there are theoretical concerns about its accuracy when the mother or infant is on ART; uptake of this technology globally has been somewhat limited.

- **Recombinase polymerase amplification**: is a novel, isothermal, nucleic acid amplification technique that detects DNA or RNA using enzymes instead of the complex thermal cycling instruments of PCR. While still in initial development phases, it shows much promise. Its advantage is that it may be performed at PoC in rural health clinics and detects (within 15 minutes) the major HIV-1 strains circulating globally(29).

**Laboratory levels**

Where NAT is conducted on **high throughput technologies (versus PoC testing)** NAT requires a dedicated higher laboratory space at a district or regional health lab or higher (see Figure 4 below). With the scale up of PoC testing, the future may see the shifting of NAT from the national reference laboratories to hospital-based and district laboratories and health facilities.

Most countries have a large regional laboratory or national reference laboratory that either **conducts** all NAT in-country and/or **monitors** all NAT in-country. All countries should also have in place a QA (also referred to as quality management) system to ensure that laboratory test results are correct every time.
Indeterminate test results
A new WHO recommendation (as of July 2018) addresses the decrease in prevalence and its effect on positive predictive value (PPV) of infant virological testing. PPV of a test, or the ability of the test to be sure that a positive result is really positive, is not intrinsic to the test: it depends on prevalence. This coupled with low levels of virus found in some infected infants has led to an increase in false-positive results and the introduction of the concept of an indeterminate result. An indeterminate result or range is a range of viral copy equivalents and a cycle threshold (CT) value that would be too low to accurately diagnose as positive. WHO and others conducted a systematic review that found of 14,753 non-negative test results (non-negative refers to any positive or indeterminate test result), 2,436 (16.5%) were indeterminate (unpublished data). Another study reported by WHO found that 76% of infants with an initial indeterminate test result were negative on repeat testing. Had these indeterminate results not been repeated, these infants might have been started on lifelong treatment unnecessarily (3).

To minimize the number of indeterminate results, WHO recommends:

- Laboratories use the approximate equivalent of a CT of 33 on the Roche COBAS® Ampliprep/COBAS® TaqMan® HIV-1 Qualitative Test v2.0 assay for further testing. This represented a balance between the proportion of infants living with HIV that would be incorrectly identified as indeterminate and the proportion of HIV-uninfected infants that would potentially start treatment unnecessarily. (CT's represent the PCR cycle at which amplification is first observed and are inversely correlated to the amount of virus in the sample.) (3). Note: Each platform is calibrated to known WHO reference standards and sets CT cutoffs for detected and not detected. These cutoffs are different for each platform. The new WHO recommendation of evaluating which positives are deemed falling within the indeterminate range is only possible

The laboratory conducts a repeat test on the SAME sample using the additional available DBS or remaining whole blood. This procedure will resolve the majority (>95%) of indeterminate results. Should the test result be indeterminate a second time, the laboratory should contact the health facility to request that the infant return to the facility for collection of a new sample within four weeks (3). For more information, see Appendix 12.

Quality assurance
QA is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible. Important elements of a QA system are discussed below.

In most countries referral labs (the National Reference Laboratory and/or Regional Laboratories) conduct all NAT in-country and/or monitor all NAT in-country. QA checklist for infant HIV testing laboratories includes but is not limited to:

1. Are laboratory technical personnel trained on the test they perform? Is this documented?
2. Do laboratory technical personnel demonstrate competency for the test they perform annually?
3. Are QC results monitored and documented including external QC specimens when possible? QC includes the measures taken during each test run to verify that the test is working properly. This includes ensuring correct temperature conditions, tracking of expiration dates for reagents necessary to run the assay, kit controls, external controls, etc. QC indicates whether the test run was valid and has produced acceptable results. QC does not, however, indicate that the results are accurate, nor that they have been reported properly.
4. Are scheduled calibration and maintenance of instrument/device performed? Is this documented?
5. Are reagents and supplies inventory performed on a regular basis and ordering based on projected need? Is this documented?
6. Are analysers/assays validated at each testing site? Is this documented?
7. Are the room temperature and humidity in all laboratory rooms recorded on a daily basis?
8. Are SOPs available, reviewed and updated annually? Is this documented?
9. Is occurrence management conducted to record any unusual and unexpected occurrences, e.g., instrument failure, loss of power, sample mix-up in the laboratory, and the corrective actions?
10. Are results returned to clinicians in a timely fashion (within 7 days for birth testing, within 28 days for all other infant HIV testing)? Is this documented?
11. Is the result turnaround time from the time of DBS collection to the time of DBS arrival at the laboratory tracked? Is this documented?
12. Is the result turnaround time from the time of DBS arrival at the laboratory to the time of returning laboratory results back to clinicians tracked? Is this documented?
13. Are the final testing results reviewed and signed off by the laboratory supervisor?
14. Does the laboratory participate in any external PT programs (see below)?

The items in the above list will help the infant HIV testing laboratory move towards to ISO 15189 accreditations.

External quality assessment (EQA) schemes
All laboratories should participate in an EQA. EQA schemes analyse the accuracy of the entire testing process from receipt of samples, testing of samples, and reporting of results. Failure with EQA usually indicates that there is a problem with QC procedures (31). An EQA is also known as PT and is an external evaluation (i.e., undertaken by a person or agency that does not work for the laboratory).

- For high throughput laboratories: an external provider sends samples of an unknown HIV status for testing at the laboratory; the laboratory reports their results back to the external provider.
- For PoC testing sites: the reference laboratory or external provider sends samples of an unknown HIV status for testing at the PoC testing site; the PoC testing site reports their results back to the reference laboratory or external provider.

Programme Manager’s role
The Programme Manager may be part of the group responsible for ensuring that laboratory services complement the continuum of care for HIV-exposed and infected infants and children and meet national standards. The Programme Manager needs to have a basic understanding of the laboratory processes to participate in discussions on early infant testing (high throughput and/or PoC).
8. Sample Transport and Results Return

Transport of specimens
In general, an efficient sample transportation system fulfills the following criteria: scheduled, punctual, reliable, sustainable, cost effective, safe, scalable, robust, and comprehensive. Turnaround time is an issue regardless of platform including PoC and near PoC. Decentralization of testing to primary, community, or district level health care (i.e., levels other than the national level) facilities can reduce some of the bottlenecks and transport challenges of centralized high-throughput testing, however if testing takes place at a site other than the site where patient sample is taken, then transport of samples must be considered.

A fragmented, unreliable sample transportation system can result in long turnaround time, samples getting lost, high rates of sample rejection at the testing laboratory, concerns about the validity or accuracy of test results, and reduced use of the service at site level. The use of DBS minimizes certain risks associated with transporting samples, and thus the primary concern in developing a sample transportation network for infant HIV testing is minimizing turnaround time. Turnaround time is a critical factor in outcomes for HIV-infected infants.

Transport and communication issues must be carefully thought through and monitored frequently to ensure that samples are collected in a timely manner and promptly transported to the testing laboratory. Results should be returned to the caregiver:
- If laboratory testing: within 28 days
- If PoC/near PoC testing: ideally on the same day

If infant virologic test results have not been received by the health facility within 28 days of specimen collection, facility staff should phone the laboratory to enquire about the sample, ask if the result is available, and if unavailable attempt to trace the sample. If the sample was lost, the post-test appointment should be used to explain to the patient what has happened and to take another DBS sample and re-send for testing. If the result was provided via phone, the post-test session can be conducted as usual.

The various modes of transporting biological samples to a laboratory are not necessarily mutually exclusive; the strongest systems often employ different modes to satisfy needs at different levels of a national health system. Under the assumption that the local Programme Manager may have to complement an existing national courier system from time to time or for specific circumstances (e.g., testing for sick children), the following is an outline of some of the laboratory sample transportation systems used. A more detailed guide to specimen transport systems and considerations can be found in “Guidance for Developing a Specimen Transport and Referral System for Viral Load and Infant Virological HIV Diagnosis Testing” which can be downloaded at http://www.aslm.org/resource-centre/hiv-viral-load-testing/hiv-viral-load-scale-tools/
• **Courier or commercial carrier.** Federal, postal and local transport regulations must be followed if using the postal or courier services. DHL, FedEx, and other services have been used successfully but are often more expensive than public sector alternatives. Generally, DBS samples are considered non-biohazardous; however, humidity and moisture are detrimental to stability of DBS samples and accurate testing. Chemicals or other types of samples should not be packaged in the same container used for shipment of DBS samples. Couriers typically transport via some sort of van, truck, or motorcycle.

• **Motorcycle courier services.** Dedicated motorcycles could improve/provide vehicle reliability and mobility even in countries with limited or undeveloped road infrastructure, and at a cost lower than cars or trucks. Building a system that provides ongoing maintenance and management to ensure reliability is essential to reduce breakdowns and to increase usable time of motorcycles.

• **National postal system:** A national postal system typically has extensive geographical reach within a country and provides relatively regular service. Due to the stability of DBS samples, a national postal system is often a good option for DBS sample transport, but if the sample transportation system will integrate other sample types (e.g., plasma samples for VL testing), considerations around sample stability and safety must be taken into account.

• **Dedicated individual couriers.**
  - DBS samples can be hand carried by a designated person from clinical sites (or a district depot) to the laboratory on a regular basis to exchange samples for results.
  - The central laboratory might employ individuals to travel to clinical sites to gather samples and deliver results.

• **Existing delivery systems.** Countries can utilize existing health supply transportation systems to deliver samples to laboratories. Another option is to develop public-private partnerships to leverage existing distribution networks of private companies (e.g., Coca-Cola, cell phone card providers, newspapers). A thorough analysis of a potential public-private partnerships, including an understanding of risk allocation between the public and private sectors and of cost, should be conducted before this type of partnership is established.

• **Public utility vehicles:** Public utility vehicles, such as ambulances, provide an option for transport of samples and commodities. However, this is generally not an optimal option due to challenges around services and maintenance, fuel shortages, and lack of spare parts in-country and because ambulances should, in most circumstances, not be diverted from regular duties to transport samples and supplies.

• **National public transportation system (buses):** The bus is the most commonly used form of transport in resource-limited settings, and thus has the advantage of high geographical coverage. Cargo holds can be used to store samples and supplies, but regulatory hurdles may have to be overcome before this system is implemented.

As a general rule, the following considerations must be made when selecting one or a mix of modes of transport:

• Conduct a **costing** exercise to estimate the full cost of implementation and review annually.

• Ensure the process — from obtaining sample to return of result, including mode of transportation — maintains patient confidentiality and chain of custody.

• Operate with **transparency** (important if this service is contracted out).

• Put structures in place to **monitor and enforce contracts** (important if this service is contracted out).
• Develop plans for **service and maintenance** (important if this service is contracted out).
• **Train** staff on sample handling techniques and safety with well-developed SOPs that are reviewed annually.
• **Monitor and evaluate** the system to make sure that the required service is being provided.

**PoC technologies**: Where testing is provided at PoC, sites must think through the test process/flow from taking the sample to testing and return of results. This process should be outlined in the facility’s SOPs and should aim to minimize patient wait time to less than 2 hours.

**Return of results**
Even when results are returned as hard copies via courier or postal service, it is recommended that when possible, technology should be used to expedite return of results to the clinic and, in turn, to the patient. Countries have experimented with new technologies to ensure the return of results on the day that they become available at the laboratory. Examples of methods for returning results electronically include the following.

• **Short message service (SMS)**: Many countries have had success with the return of results via SMS, also referred to as text message. The SMS will function where there is mobile telecommunications network coverage. The SMS printer is a small battery-operated printer (see Figure 5) that can take a SIM card and has the capability of receiving messages without the need for a handset. SMS printers can **receive** and print test results at the health facility without computer or internet access. SMS printers are easy to use, require limited maintenance and only thermal paper as a consumable. SMS printers need to be stored in a lockable, private room or box. A SMS printer system functions as follows:
  • Reference laboratories record NAT results electronically and use a modem to send these results from a desktop computer to compatible, battery-operated printers at health facilities.
  • The infant HIV test results are transmitted via SMS.
  • The SMS printers automatically print the results.
  • Results are recorded by healthcare providers in facilities into registers and delivered to patients. More information on SMS printers can be found in “Appendix 13: Criteria for Introducing SMS Printers.”

• **Fax machine**: this is possible if the clinic has a phone line and if the fax machine can be placed in a lockable, private room or box.

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**Figure 5: Example of an SMS printer**

![Example of an SMS printer](image-url)
- **Secure webpage.** Another option is for the laboratory to develop password-protected clinic-specific webpages. Results would then be posted on the webpage by laboratory staff to be accessed by clinic staff who visit the web-based portal and input the correct password. This system is a viable option where clinics and laboratories have reliable access to the internet and where web-based results can be printed so that documentation of test result can be added to the patient medical chart. See box on EID Dashboard in Kenya in “Section 4: Retention in Care”.

- **E-mail:** This system would also rely on regular internet access. The receiving e-mail address must be password protected to protect confidentiality of results.

- **Telephone:** This method can be used where results are urgent, but there must be a mechanism to ensure confidentiality of results transmission. Given the need for hard copy documentation, phone communication of results should be followed-up with a paper printout (sent by courier or post) from the laboratory for the patient medical record. It is suggested that for all positive infant tests, the laboratory immediately notify the clinic via phone to reduce loss to follow-up of positive babies.

- **Other:** in coming years, as technology advances, it is likely that other innovative ways to expedite the return of test results will become available. For example, the Government of Malawi and UNICEF have started testing the use of Unmanned Aerial Vehicles (also known as drones) to deliver test results quickly(33).

Given the need for hard copy documentation, e-mail, phone, or web-based communication of results should be followed-up with a paper printout (sent by courier or post) from the laboratory for the patient medical chart. In many settings, test results will be returned using a combination of methods, e.g., urban clinics can access results using a web-based portal while more remote sites rely on SMS printers.

**PoC technologies:** PoC testing platforms for infant virological testing have the potential to avoid the challenges of sample transport and delayed turnaround time. However, the SOPs should clearly state how the result will be communicated to the healthcare provider; how the result will be entered into the register(s) and patient record; and how the result will be communicated to the patient’s caregiver.

**Sample/result management**
Track samples and results as they move from the setting where sample is taken to the lab and back to the clinical site where post-test counselling takes place. A Sample Transport Log facilitates tracking of samples and results with a chain of custody. When the sample is ready to ship, the healthcare provider who drew the sample records the patient name and other identifying information in the column on the left. The log includes additional columns at each point that the sample is handled — usually, driver, laboratory where the sample will be tested, and then the clinic where post-test counselling will take place. The Sample Transport Log is more efficient than the clinic registers to track turnaround time, missing results, percentage of rejected samples, and other transportation-related indicators. A Sample Transport Log is included as Appendix 14.

**Managing results**
Whether using high throughput, PoC, or near PoC technologies, healthcare staff need to have a system to manage patient results. Upon receipt of laboratory test results, all healthcare facilities are expected to enter the results in both:

- The designated register/database to inform programme monitoring and reporting; and
The patient chart: file the hard copy of result in the patient chart to facilitate communication of correct results to the patient and support patient care,

While filing results in the patient chart facilitates communication of correct results to the patient and supports patient care, recording results in the database/register facilitates programme monitoring and reporting.

Training healthcare providers on SOPs—and providing job aids or other materials as reminders—on the steps to take when an infant HIV testing result is returned to the facility (e.g., transfer the information from the patient result form to the facility register, contact the patient’s caregiver to inform her/him that the results are ready at the facility, deliver results to the caregiver and explain next steps, etc.) can improve patient tracking and overall care.

Tracing late results
Health facilities must have a protocol for identifying and tracking late results. Delayed results are usually identified by using the Sample Transport Logs (see Appendix 14) or another register such as a DBS Specimen Tracking Register or Baby Testing and Follow-up Register. Results not received within 4 weeks (or as per national guidelines), should be considered late. Every facility will need to have a protocol indicating who will contact the laboratory to enquire about the delayed results and how (fax, e-mail, SMS, or telephone).

Someone in the laboratory will assume responsibility for promptly responding to delayed result inquiries, preferably while the clinic healthcare provider is still on the phone, in case a sample is truly lost and needs to be collected again. Ensuring good communication will reduce unnecessary retesting (which is burdensome for both the laboratory and patient), reduce unclaimed test results, and expedite healthcare for infants.

Confirmatory testing
All infants and young children testing HIV positive (by NAT) need to be retested to confirm the initial test result, whether testing was undertaken at a centralized high-throughput laboratory or at PoC. National guidelines should always be followed.

- Confirmatory testing includes collection of a new specimen for NAT before/at ART initiation.
- Confirmatory testing reduces the chance of misdiagnosis due to technical or clerical errors, including specimen mix-up through mislabelling and transcription errors, specimen contamination, or device error.
- The infant/child should initiate ART while awaiting confirmatory test results(4). Do not postpone ART initiation for the results of the confirmatory test.

Programme Manager’s role
The Programme Manager may need to assure adequate sample transport and results return processes and address challenges if these systems fail to meet national standards. The more s/he understands about how the system should work and the range of potential solutions, the more likely the Programme Manager will be able to identify creative solutions to the issues should they arise.
9. Forecasting and Supply Chain Management

A robust supply chain for infant HIV testing commodities is critical to ensure that infant HIV testing interventions operate effectively and without disruption. Unlike the provision of treatment for an illness or condition—which requires the availability of only one or a few drugs—laboratory testing typically requires many different consumables and pieces of equipment. This requirement, the limited standardization in the deployment of laboratory technology (leading to different laboratories purchasing different diagnostic systems from different manufacturers—each requiring specific reagents and technical support), and the inadequate attention given to logistics information systems, including laboratory items, make procurement of laboratory technology far more complicated than that of medicines.

The infant HIV testing supply chain system

Supply chains are composed of numerous logistic processes to ensure efficient flow of commodities. Good management of supply chain processes ensures access to(34):

- The RIGHT commodities
- In the RIGHT quantities
- In the RIGHT condition, delivered
- To the RIGHT place
- At the RIGHT time
- For the RIGHT cost.

Figure 6: Supply chain system (From USAID: DELIVER PROJECT)

Figure 6 illustrates that the supply chain (or logistics) system is circular. Each activity within the cycle (customer service, product selection, quantification, procurement, and inventory management) is affected by the other activities. All supply chain processes are data driven, with consistent site-level reporting and high-quality data serving as a critical determinant of effective logistics management. As a result, a supply chain can only be as strong as its weakest link.

Coordination, data sharing, and effective supply planning between the multiple partners who may be responsible for supply procurement is essential to avoid stockouts and shortages. Ensuring optimal order placement, understanding product lead times for delivery, and accurate forecasting serve as cornerstone of commodity security. Overstocks should be avoided, as expiring test kits and reagents are costly for the programme. It is critical to ensure that planning committees include all parties responsible for procurement and distribution of supplies. The following is an overview of commodities required along the infant HIV testing continuum, forecasting and quantification, ordering, and stock management.

**Infant HIV testing commodities**

To conduct infant HIV testing, whether PoC or high throughput technologies, commodities are required at both the health facility, where patients are seen, as well as at the laboratory, where samples are processed. At the health facility, materials are needed to collect specimens from HIV-exposed infants and to transport the samples to a molecular laboratory for analysis. In the laboratory setting, testing reagents and associated consumables are needed to prepare the samples for analysis and to process them. The following discussion focuses on the commodities needed at the health facility to collect, dry, package, and send DBS for infant HIV testing, under the assumption that most sites are collecting DBS specimens for processing at an off-site laboratory.

**Products for PoC or near PoC testing**

PoC or near PoC testing require far fewer products over conventional high throughput testing technologies. These products are cartridge based and require blood collection commodities with the patient sample normally being transferred to testing cartridges on site, which are then placed into the instrument to perform testing. Appropriate stock management and monthly reporting of consumption and stock on hand is critical due to the shorter shelf life of these commodities over traditional testing products. These products come in a variety of pack sizes; therefore, it is important to align average consumption rates with the appropriate pack sizes to avoid overstocking and excessive expiries.

**Bundled products, high throughput technologies**

Where high throughput technologies are used, over 60 individual commodities are required along the infant HIV testing continuum. Some of these items, such as the DBS filter paper collection cards used to collect blood samples, are specialized. Other items, such as cotton swabs, are generic. In the early stages of establishing infant HIV testing programmes, countries would procure these 60+ items individually, which made ordering and distribution a complex endeavour. Furthermore, a stock out of any single item could compromise the quality of samples, or prevent the collection and/or processing of NAT samples altogether.

For ease of procurement and distribution and to ensure the quality of commodities, suppliers have developed bundled products. Bundled products contain all of the necessary items required at the sample collection site or at the testing laboratory in a convenient package. For example, a DBS kit
for clinic use contains all items required to collect, dry, and ship either 1, 20, or 50 DBS samples to the laboratory (e.g., powder-free gloves, lancet, DBS card, etc.) in a sealed bag; these single use bundles are recommended. The only component within the kits that expires is the DBS filter paper card, which has an expiry printed directly on it. DBS sample collection kits have a shelf life of up to 2 years. Do not use DBS cards that do not have expiry dates.

By ensuring that all items needed are available to healthcare providers (or laboratory technicians) in a single kit or box, bundled products for infant HIV testing have simplified the supply chain and reduced the occurrence of testing delays due to the stock out or misappropriation of a single item. By delivering improvements in supply chain and increased confidence in the quality of supplies, the use of “bundled products” has contributed significantly to the scale up of infant HIV testing services in many resource-limited countries.

The benefits of bundled products include:

- As long as a bundle supplier has a proven record of accomplishment, bundles provide QA of the items within. This is especially crucial for certain items that must adhere strictly to quality standards (e.g., lancets, powder-free gloves) to ensure that proper care is delivered to the infant and that the sample is prepared correctly (thus mitigating the risk of the sample being rejected at the laboratory).
- Bundles reduce the risk of items, such as gloves, being re-appropriated or re-purposed for other services. This is an especially crucial factor in countries where VL testing will scale up using DBS samples.
- Bundles reduce stock outs and wastage.
- Bundles reduce interruptions to DBS sample collection and thus to testing.
- Distribution of DBS kits to sites provides a country the ability to scale-up services quickly at new collection sites/ facilities.

**Forecasting**

If commodities are not accurately forecasted, the procurement of infant HIV testing commodities will not be consistent with programme needs. This may result in infant HIV testing programs not being able to function optimally, jeopardizing patient care.

Quantification is an exercise that consists of estimating the total commodity need in accordance with a budget and national/sub-national targets. A strong quantification can help avoid stock outs and wastage of excess stock. Consideration should be made for initially increasing NAT and VL testing volumes at new PoC sites, on the assumption that, as availability of a PoC device becomes known in the community, demand might increase. However, this must be carefully managed to avoid excess quantification.

For PoC and near PoC devices as part of rollout, the forecast should take into account rolling implementation by adding the quarterly volumes per site. Once a site is implemented, it should be assumed that it will continue to test in all the subsequent quarters over the forecast period.

Quantification requires a number of inputs:

- **Consumption and service data:** These forecasts rely on historical average monthly consumption and testing data to assist in predicting future testing demand and/or product usage. This forecasting approach relies on historical data, which may not be available for new
programs. In this case, similar tests or product introductions could be used as a proxy to estimate demand.

- **Demographic (morbidity) and target-based** forecasting methods are used in conjunction with service and consumption base forecasts when possible. When sites do not have historical consumption or testing volumes, forecasts can apply the national NAT/VL coverage rate to the PMTCT population or ART cohort registered at the facility, and apply a scale up or implementation rate to estimate product needs. However, this must be carefully managed to avoid excess quantification. Additional information could include statistics about the epidemic (e.g., HIV prevalence among pregnant women, mother-to-child-transmission rates, loss to follow up rates, etc.).

- **Wastage**: This data is comprised of sample rejection rates at the testing laboratories and loss in the supply chain.

- **Lead times**: This data accounts for amount of time necessary for products to arrive once an order is placed.

- **Stock on hand**: This is the measure of existing stock in country and includes any orders that have been placed and are in transit.

- **Buffer stock**: This is an estimate of stock kept to guard against the effects of expected events (e.g., increased demand, etc.) and to account for lead times when orders are placed. Typically, a country should establish minimum and maximum stock levels (buffer stock), with orders placed prior to dropping below minimum stock levels (minimum/maximum stock levels typically stand at 3–6 months of stock).

The basic steps of the NAT quantification exercise are as follows:

1. Calculation of the need, or the total demand in terms of the number of DBS samples to be collected and the number of NAT to be performed, is based on the following:
   - The number of HIV-exposed infants (estimated based on the HIV prevalence in pregnant women)
   - (Algorithm) Number of tests in algorithm to confirm HIV-positivity (Y/N)
   - (Algorithm) Positive infants are tested again following the same algorithm (confirmatory testing) to confirm HIV-positivity (Y/N)
   - (Algorithm) Number of tests that are in the indeterminate range and require further testing
   - (National recommendations) Negative infants are tested again at 9 months of age
   - (National recommendations) Negative infants are tested again at 18 months of age or 3 months after the end of breastfeeding (whichever is later) (Y/N)
   - National testing target
   - % of target realistically achievable based on the latest information available
   - % of HIV-exposed infants LTFU between the first and confirmatory tests
   - % of HIV-exposed infants LTFU between the first testing period and the end of breastfeeding
   - Number of sites collecting samples for infant HIV testing
   - Consumption data (may not always be available)
   - Have significant policy or programmatic changes that could affect infant HIV testing volumes been factored in? (e.g., case-finding strategies for HIV-exposed infants)
   - Has your area experienced any stock outs or other supply chain-related challenges?

2. Adjustment of the need to incorporate wastage and controls.
3. Translation of the need into the total number of product packs to be procured to fulfil demand.

NOTE: Additional forecasting assumptions and data requirements, and supply chain considerations specific to PoC and near PoC devices as part of scale-up can be found at UNICEF’s website: HIV Point-of-Care Diagnostics Toolkit (https://www.childrenandaids.org/poc-toolkit-page)

Staff involved in forecasting and quantification are usually also responsible for ordering and procurement of infant HIV testing commodities for clinics. In most cases the ordering and delivery of testing commodities is integrated into existing centralized ordering mechanisms and supply chain so that ordering of supplies for testing becomes a prioritized, routine exercise like all other essential health commodities.

**ForLab quantification tool**
ForLab is a standardized, open-source software tool with clearly defined forecasting requirements. ForLab improves the ability of programmes to collect and analyse data to accurately forecast commodity needs for all laboratory-based commodities, inclusive of PoC, near PoC, and conventional based instruments. ForLab performs long- and short-term forecasts using a mixed methodology, triangulating demographics, targets, service, and consumption data for a best fit forecast. It is available for download from: http://www.forlabtool.com/

**Stock management and tracking**
Stock status monitoring is essential to track months of stock on hand and consumption rates to ensure a full commodity pipeline. Data is required to mitigate the risk of stock outs and expiries. Maintenance of a stock status tool at a central level—ideally by the team responsible for forecasting and quantification as well as ordering—is advisable.

Stock monitoring and consumption tracking will naturally feed back into forecasting and quantification exercises and ensure timely adjustments to next order quantities as part of active supply planning, as well as improving the ability to accurately predict and plan for future need.

**Programme Manager’s role**
Programme Managers, as part of an interdisciplinary team, should ensure that forecasting and supply chain management systems meet national standards and address challenges if these systems fail to meet national standards. The more the Programme Manager knows about forecasting and supply chain management, the more s/he can contribute to improving the system when needed.
10. Linkage of HIV-infected Infants to ART

Every site that provides infant HIV testing services will need to plan where HIV-infected infants will receive HIV treatment. Many sites that offer infant HIV testing services will also provide treatment to infants and children diagnosed with HIV, but where HIV treatment is not available on-site, clinic staff must know their designated paediatric HIV treatment site and the linkage procedures (including days/times of operation and what to bring to a first appointment). Ideally, infants should be presented at the HIV treatment site for evaluation and management on the day of diagnosis for timely initiation of ART.

Whether the linkage is for HIV care and treatment or for another service such as nutrition counselling or TB care, there are two steps to the development of effective linkages:

1. Establish a relationship between service delivery points/sites for infant HIV testing and HIV treatment

The infant HIV testing site establishes a relationship with an internal (within the same facility) or external health facility to offer a package of care for their patients. This agreement between providers can be informal or formal. Informal agreements are unwritten agreements between providers or Programme Managers of two or more health facilities. Formal agreements are based on the same conversation between providers or Programme Managers, but the terms of agreement are recorded in a memorandum of understanding (MOU), linkage agreement, or some other documentation signed by both parties. A template for a linkage agreement or MOU is in the box on the next page. These agreements outline services provided by both organizations and the expectations of both providers. Although these agreements are often required as part of a proposal process, rarely do they involve an exchange of funding. Tips for making linkages work:

- Whether the linkage agreement is formal or informal, it is important that all healthcare providers and administrative staff are familiar with this linkage agreement. Even the receptionist should know where children with HIV can go for ART, for nutrition support, or for TB care, etc.
- Healthcare providers should know where referral agencies are located, their addresses, phone numbers, and how to get there.
- Healthcare providers will also need to know what the patient will need to bring with her to get her child enrolled in care (e.g., antenatal card, child health card, birth certificate, documentation of HIV test results, national health number), and whether the patient will have to pay for services.
- Where possible, healthcare providers should visit the sites to which they refer their patients, become familiar with the staff and the building so that they can respond to patient questions.
### Format for the linkage agreement/MOU

A linkage agreement can be as simple as a single page or it can be longer and more complex. At a minimum, it should include the names of the agencies entering an agreement, an overview of the services that they will provide for each other’s patients, dates when the agreement commences and expires, and agency signatures. A more detailed linkage agreement might include the following sections.

- **The introduction section** of the MOU helps the reader to understand the agreement content. It describes the need and the agencies involved (e.g., “a commitment to integrate service delivery for HIV-infected infants and children through working relationships between X and Y organizations”). It can also briefly describe in one or two sentences why it is necessary to work together.

- **The purpose section** should be a concise statement discussing the intention or purpose of the services to be provided under the agreement. For example: “The purpose of this Linkage Agreement is to ensure to the maximum extent possible that infants and children living with HIV receive comprehensive health services, including, but not limited to the following: primary care services, ART, adherence assessment and support, cotrimoxazole preventive therapy, routine laboratory monitoring, routine follow up, and referrals for specialty care. All care will meet standards described in the national guidelines.”

- **The scope section** lists the agencies to be included in the agreement and describes their relationship.

- **The definition section** describes the operational and technical terms associated with the agreement. Providing definitions will help avoid confusion and uncertainty.

- **The policy section** of the MOU briefly describes circumstances under which the agreement will be used. This section can also mention activation, timing, and other circumstances.

- **The user procedure requirements section** outlines the obligations of the agreement. For example: “X agency agrees to see all newly diagnosed infants referred by the infant HIV testing site. X agency will see these patients and their caregivers within 24 hours of a referral.”

- **The oversight section** describes how the infant HIV testing site will provide oversite or recommendations that affect policy and whether other agencies accept or reject these recommendations.

- The responsibility for **Standard Operation Procedure (SOP) compliance section** assigns responsibility to agencies to ensure SOPs for the care and treatment of infants with HIV are followed.

- **The updates to the MOU section** describes how updates can be made to the MOU. It includes information such as who has the authority to update the MOU, how updates will be made, and how participating agencies will be notified of updates.
2. **Infant HIV testing point ensures that an HIV-positive infant is enrolled in HIV treatment and initiated on ART**

The patient is then linked or escorted to that clinic for services. It is the responsibility of the healthcare provider to help the patient overcome any barriers to attending a clinic to which s/he has been linked and returning to the clinic for follow-up visits. Where possible, the client should be accompanied to the referral organization on the same day. Some clinics have vans and drivers to escort clients to a referral organization, others engage lay providers, navigators, or outreach workers to accompany them. Where this is not possible, the referring healthcare provider should phone the agency to which their patient is being referred to make an appointment for the patient.

**Tracking referrals.** A referral cannot be considered successful unless patients actually attend the agency to which they have been referred. Unless the clinic (where testing took place) has escorted or driven a patient to the HIV treatment site (or other agency), how do you know if s/he ever attended? Tracking referrals is always a challenge; a challenge that programme managers should discuss with all provider agencies in their area. It is important not only that patients attend the agencies to which they are referred (perhaps even a matter of life or death), but also that the agency to which the patient is referred provides the original site with feedback.

This is where a web-based database is clearly advantageous to the traditional paper-based records. Electronic databases, stored on central servers, facilitate sharing of data between providers. One can find out if a patient attended for HIV treatment, just by checking the electronic database. If databases are not available, then systems that facilitate the sharing of patient information might include:

- Patient held documentation (e.g., referral forms): such documentation would be provided at the original site and submitted to staff at the, for example, HIV treatment site. The HIV treatment site would complete the referral forms confirming that the patient attended for care and then return the referral form to the original site. The referral form may or may not require a summary of key findings. Referral forms can be returned to the original site in monthly or weekly batches.
- Where patients are assigned unique identifiers that are standard throughout the health system, patient records can be matched at a district-level and referrals confirmed in this manner.

**Documentation**

Infants referred to an HIV treatment site will need to bring with them documentation of HIV testing and results as well as their child health card. The child health card supports continuity of care as it stays with the patient from one facility to another. The following information must be clearly and accurately documented on the child health card to create a seamless referral for services:

- Date of infant HIV testing
- Type of test used (NAT, RDT, or other)
- Result of test (often denoted by ‘R’ [reactive] or ‘NR’ [non-reactive] and marked in such a way, such as circling, so that results cannot be altered later)
- Services initiated (cotrimoxazole prophylaxis, nutritional services, VL testing, others)
- Referrals made: Where the infant should be seen for further HIV services and when they should arrive at that location
The more specific this documentation can be, the better the chance for a successful linkage to care and treatment. One staff member needs to take responsibility for ensuring that infants diagnosed with HIV get into care and initiate ART in a timely manner (20).

**Programme Manager’s role**

It is the Programme Manager’s role to ensure that every site in his/her jurisdiction has a plan and SOPs to guarantee that every HIV-infected infant is enrolled in HIV care and started on ART. The Programme Manager will also be responsible for ensuring that health facilities remove barriers to linkages and track the success of their linkages.
11. Community Engagement

It is important that clinics providing PMTCT and infant HIV testing services have close linkages with the community. Ideally, when a new clinic or a new service is initiated, it would be planned in collaboration with the wider community. Even where a clinic or service is well-established, multiple lines of communication with the wider community are essential. Programme Managers, or their delegates, should consider:

- Meeting with community leaders at least annually to talk with them about national and local efforts to prevent MTCT, the successes of the PMTCT programme, the importance of infant HIV testing. Discuss ART, what it is and why it is effective, using terminology that community leaders understand. Listen to them about their concerns and reservations about the programme, respond to their questions and concerns.

- Participating in community meetings and community gatherings to discuss HIV, PMTCT, and the comprehensive package of care for HIV-exposed infants including HIV testing, and ART for mothers and babies.

- Training/orienting existing lay providers and community volunteers to assist in the clinic setting. They can undertake non-clinical work (administrative or errand running) as well as patient support including outreach work (community education as well as outreach to patients who have missed appointments) and basic patient education. (See content on lay providers in “Section 5: Healthcare Provider Selection and Training”.)

- Starting support groups for mothers with HIV at the clinic or in a community setting.

- Involving mothers or fathers who are openly living with HIV to strengthen facility-community linkages by, for example, speaking at community or church meetings, making presentations in the schools, and meeting with community leaders.


Community resource directory

To support the provision of effective referrals, healthcare providers, lay providers, and other clinic staff (including the receptionist and other support staff) need to be up-to-date on the community services available to parents with HIV and their children. A regularly updated community resource directory can facilitate referrals. The Programme Manager can support the development of this directory by assigning one person to take responsibility for writing it and keeping it up-to-date and by allocating funding, if necessary, for researching and maintaining the webpage on which it lives, and/or photocopying.

The resource directory should list the agencies in the local continuum of care for people living with HIV. It should include days/times services are offered, fees, documentation required at the initial visit, address, phone number, contact person, etc. The community resource directory can be on line or printed, it should be distributed to healthcare providers and clients and/or posted in waiting rooms, examination rooms and counselling spaces for easy reference.
Client/consumer/community advisory boards (CABs)
Some healthcare facilities or clinics may be interested in establishing a formal mechanism to facilitate feedback from clients and the wider community through the establishment of a CAB. CABs are autonomous bodies that advise the clinic on service quality and gaps in care. They also make recommendations on how to improve service provision. CABs:
- Usually include 5–20 members. 7–9 is typical, most or all of whom are clients, caregivers, or other community members affected by HIV. Members should represent a wide range of the clients served by the clinic.
- Typically meet every other week at first and monthly once established
- Have a direct line of communication with the Programme Manager. Typically, a high-level clinic manager attends every meeting.
- Are guided by a set of by-laws developed by members and approved by the clinic they advise.

Programme Manager’s role
Looking at the wider system of care, the Programme Manager may want to take a role in ensuring that community linkages between healthcare services and from/to healthcare facilities and non-governmental services function well and meet patient needs. The Programme Manager has a key role in ensuring the community is engaged in their healthcare services and that those services meet the community’s needs.
Appendix 1: Algorithm for Risk Assessment

This algorithm was developed to support risk assessment at the time of delivery and to help identify infants at high and low risk for HIV acquisition.

Infants at low risk should be given standard prophylaxis (nevirapine or zidovudine alone for 4–6 weeks) while those at high risk should be given enhanced postnatal prophylaxis (also referred to as ePNP). To navigate this algorithm successfully, clinicians will need to know a number of parameters from the mother’s antenatal chart:

- HIV status and date of last HIV test (to identify status and need for testing or retesting at delivery);
- If known to be positive, and ART started, date of ART initiation;
- If VL collected, date of sample collection relative to delivery and VL result.

Programs should consider incorporating a maternal VL test at or around 36 weeks’ gestation, ensuring that the turnaround time is short enough to have a result available by the expected delivery date.

Source: WHO, 2018 (3).
### Appendix 2: First-Line Regimens for Paediatric Populations

<table>
<thead>
<tr>
<th></th>
<th>Neonates (&lt;4weeks)</th>
<th>Children (&gt;4weeks-9 years )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred</strong></td>
<td>AZT + 3TC + RAL</td>
<td>ABC + 3TC + DTG[^2]</td>
</tr>
<tr>
<td><strong>Alternative</strong></td>
<td>AZT + 3TC + NVP</td>
<td>ABC + 3TC + LPV/r</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ABC + 3TC + RAL[^3]</td>
</tr>
<tr>
<td><strong>Special situations</strong></td>
<td>AZT + 3TC + LPV/r[^1]</td>
<td>ABC + 3TC + EFV[^4] (or NVP)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AZT + 3TC + EFV[^4] (or NVP)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AZT + 3TC + LPV/r (or RAL)</td>
</tr>
</tbody>
</table>

[^1]: If starting after 2 weeks of age
[^2]: For age and weight groups with approved DTG dosing
[^3]: RAL can be used as an alternative regimen if LPV/r solid formulations are not available
[^4]: EFV should not be used for children younger than 3 years

3TC=lamivudine, ABC=abacavir, AZT=zidovudine, LPV=lopinavir, NVP=nevirapine, r=ritonavir, EFV=efavirenz, RAL=raltegravir, DTG=dolutegravir

Source: WHO, 2018 (35).
Appendix 3: WHO Simplified EID Algorithm

Notes:

a. Based on 2016 WHO Consolidated ARV Guidelines, addition of NAT at birth to the existing testing algorithm can be considered.

b. PoC NAT can be used to diagnose HIV infection as well as to confirm positive results.

c. Start ART without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase; retesting after a first positive NAT is hence important to avoid unnecessary treatment, particularly in settings with...
lower transmission rates. If the second test is negative, a third NAT should be performed before interrupting ART.

d. For children who were never breastfed, additional testing following a negative NAT at 4–6 weeks is included in this algorithm to account for potential false-negative NAT results.

e. The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month test is conducted earlier than 3 months after cessation of breastfeeding, infection acquired in the last days of breastfeeding may be missed. Retesting at 18 months or 3 months after cessation of breastfeeding (whichever is later) should be carried out for final assessment of HIV status.

f. If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding. If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months. Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants younger than 18 months of age NAT should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirms infant is infected.

Source: WHO, 2018 (3).
Appendix 4: Register Examples: Integrated Mother-Baby Pair Register and HIV-Exposed Infant Birth Cohort Register

HIV-exposed infants (HEI) can be monitored in different types of registers. Two main types used by PMTCT programs are:

1. Integrated Mother-Baby Pair Registers
2. HEI Birth Cohort Registers

The main advantages and disadvantages of the two register types are summarized in the table below:

<table>
<thead>
<tr>
<th>Register Type</th>
<th>Advantage</th>
<th>Disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mother-Baby Pair Register</td>
<td>Clinically useful to track mothers and their infants together and make sure both are getting the necessary follow up</td>
<td>Difficult to monitor longitudinal outcomes for infants (e.g., infant testing by 2 months or determination of final outcome) because register is organized by enrolment of the mother and the infants are born at various times relative to maternal enrolment</td>
</tr>
<tr>
<td>HEI Birth Cohort Register</td>
<td>Easy to monitor infant longitudinal outcomes because each register page is organized by infants’ month/year of birth</td>
<td>Cannot see maternal and infant information easily in one place</td>
</tr>
</tbody>
</table>

Example 1: Integrated Mother-Baby Pair Register, Ethiopia

Source: Federal Democratic Republic of Ethiopia, Ministry of Health

Example 2: HIV-Exposed Infant Birth Cohort Register, Kenya

Source: Ministry of Health, Kenya

Click on the icons above to view the HIV-exposed Infant Register
Appendix 5: Laboratory Activity Monitoring

High throughput testing and near PoC technologies
It is highly recommended that laboratories use electronic Laboratory Information System (LIS) for sample accessioning, testing, and results management. For sample management, each patient should have a unique identifier (ID) and each sample should also have its own unique ID. The ID system should be designed in a way that samples from the same patient, collected at different times, can be linked. When laboratory testing results are entered into the LIMS, the results entry should be always verified by another laboratory staff member to avoid results entry errors.

PoC testing technologies
Where PoC testing is taking place, results will need to be recorded in a paper-based testing register/log or the (electronic) database as well as the patient database/register used for recording and tracking PMTCT services and/or HIV-exposed infant care (e.g., the Baby Testing and Follow-up Register/Log). In addition, all results should also be recorded in the individual patient chart. File hard copy of result in patient chart.

All testing technologies
The testing registers/databases for all testing technologies should include columns that capture both testing and retesting for verification, including the following columns/fields:

First HIV testing event
- Date of receipt of sample
- Site name/identification number and name/identification number of provider (tester) conducting the first testing event
- Date of first testing event
- Test 1 (Kit name, Lot number, Expiry date)
- First testing event result
- Results of kit controls and any externa controls utilized to monitor the assay

Confirmatory testing
- Date of receipt of sample
- Site name/identification number and name/identification number of provider (tester) conducting confirmatory testing
- Date of confirmatory testing
- Retest: Test 1 (Kit name, Lot number, Expiry date)
- Confirmatory testing result
- Final result
- Results of regular QC
### Appendix 6: Infant Testing and Linkage to ART Global AIDS Monitoring Indicators

<table>
<thead>
<tr>
<th>Title</th>
<th>Explanation</th>
</tr>
</thead>
</table>
| Percentage of infants born to women living with HIV receiving a virological test for HIV within two months of birth | Numerator: Number of infants who received an HIV test within two months of birth during the reporting period  
Denominator: Number of pregnant women living with HIV giving birth in the past 12 months  
Data source: Health facility or laboratory data |
| Percentage of HIV-positive infants that are initiated on ART.      | Numerator: Number of HIV-positive infants initiated on ART  
Denominator: Number of HIV-positive infants identified  
Data source: Health facility data (registers/electronic medical record) |
| Percentage of HIV-exposed infants with a final outcome at a designated age/time point. Of those with final outcome, percentage of HIV-exposed infants within each outcome category. | Numerator: Number of HIV-exposed infants with a final outcome  
Outcome options: HIV-positive, HIV-negative, LTFU, transfer out, died, still breastfeeding/exposed  
Denominator: Number of HIV-exposed infants in the birth cohort  
Data source: Health facility data (registers/electronic medical record) |

Source and further information on this indicator: UNAIDS, 2017 (36).
Appendix 7: Example Dashboard from National Infant HIV Testing Programme

The following graphs were developed from the monthly site reports collected by the National AIDS/STD Control Programme (NASCOP), Ministry of Health, Government of Kenya. [http://eid.nascop.org/](http://eid.nascop.org/)

### National turnaround time in days

![Graph showing national turnaround time in days](image)

### Testing trends, initial PCR (2017–2018)

![Graph showing testing trends, initial PCR (2017–2018)](image)
EID outcomes (2018)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Total Tests</th>
<th>Positive (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total EID tests</td>
<td>58,403</td>
<td>2,081 (3.6%)</td>
</tr>
<tr>
<td>Initial PCR</td>
<td>37,313</td>
<td>1,209 (3.2%)</td>
</tr>
<tr>
<td>Repeat PCR</td>
<td>18,790</td>
<td>330 (1.8%)</td>
</tr>
<tr>
<td>Confirmatory PCR</td>
<td>2,300</td>
<td>542 (23.6%)</td>
</tr>
<tr>
<td>Actual infants tested (based on unique IDs):</td>
<td>52,921</td>
<td>1,388 (2.6%)</td>
</tr>
<tr>
<td>Infants ≤ 2 M positive</td>
<td>17,357</td>
<td>346 (2%)</td>
</tr>
<tr>
<td>Above 2 years tested</td>
<td>308</td>
<td>23 (7.5%)</td>
</tr>
<tr>
<td>Rejected samples</td>
<td>400</td>
<td>0.7%</td>
</tr>
<tr>
<td>Median age of testing at initial PCR:</td>
<td>3</td>
<td>Average sites sending:</td>
</tr>
</tbody>
</table>
Status of actual confirmed positives at site (2018)

- Initiated on treatment: 789 (89%)
- Lost to follow up: 30 (3%)
- Dead: 39 (4%)
- Transferred out: 0 (0%)
- Other reasons (e.g. denial): 22 (2%)

EID outcomes by age (initial PCR) (2018)

- 0-2 months: 17,567
- 2-9 months: 12,064
- 9-12 months: 3,898
- 12-24 months: 3,206
- Above 24 months: 271

Actual infants tested positive validation at site outcomes (2018)

- Actual infants tested positive: 1,388
- Actual infants validated at site: 973 (70.1%)
- Actual confirmed positives at site: 884 (1.7%)
EID outcomes by entry point, initial PCR (2018)

- **MCH/PMTCT**: 25,633
- **CCC/PSC**: 2,843
- **Maternity**: 1,075
- **OPD**: 470
- **Other**: 229
- **No Data**: 280
- **IPD**: 215

EID outcomes by mother pmtct regimen, initial PCR (2018)

- **PM9**: 7,480
- **PM10**: 6,459
- **PM3**: 5,186
- **PM6**: 1,686
- **PM7**: 1,63
- **PM9**: 727
- **PM11**: 202
- **PM12**: 221
- **PM13**: 156
- **PM14**: 118
- **PM15**: 74
- **PM16**: 55

Legend:
- **Positive**
- **Negative**
EID outcomes by infant prophylaxis (initial PCR) (2018)
County outcomes (2018)
Appendix 8: Sample PMTCT Page for Child Health Card

The PMTCT pages of the Child Health Card or Chart can assist with tracking receipt of each component of the comprehensive package of care for HIV-exposed infants. Below are the PMTCT pages from the South African “Road to Health Chart”

<table>
<thead>
<tr>
<th>PMTCT/HIV INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child’s first name and surname:</td>
</tr>
<tr>
<td>Child’s ID Number:</td>
</tr>
<tr>
<td>Signature of consent:</td>
</tr>
<tr>
<td>Date:</td>
</tr>
</tbody>
</table>

**Fill in this section on discharge from Midwife Obstetric Unit (MOU) or obstetric ward or at first subsequent visit if not yet done**

<table>
<thead>
<tr>
<th>Mother’s latest HIV test result</th>
<th>Positive</th>
<th>Negative</th>
<th>To be done</th>
</tr>
</thead>
<tbody>
<tr>
<td>When did mother have the test?</td>
<td>Before pregnancy</td>
<td>During pregnancy</td>
<td>At delivery</td>
</tr>
<tr>
<td>Is the mother on life-long ART?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If yes, duration of life-long ART at time of delivery</td>
<td>&lt; 4 weeks</td>
<td>&gt; 4 weeks</td>
<td>Before pregnancy</td>
</tr>
</tbody>
</table>

**Document ARVs the mother received:**

| Did the mother receive infant feeding counseling? | Yes | No |
| Decision about infant feeding | Exclusive breast | Exclusive formula |

**Document Nevirapine given:**

| All HIV exposed infants should receive Nevirapine for a minimum of 6 weeks |
| Has the mother disclosed to anyone in the household? | Yes | No |
| Has the mother’s partner been tested? | Yes | No |

**Remember to offer testing for all the mother’s other children if not yet done**

Offer a mother with unknown HIV status a rapid HIV test.
If mother’s HIV rapid test is positive, perform an HIV DNA PCR test on infant if ≥ 6/52
## Appendix 9: Accessibility Checklist and Assessment Tool for Infant HIV Testing Services

<table>
<thead>
<tr>
<th>Questions to assess accessibility/client-friendliness</th>
<th>Answer</th>
<th>Comments/recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How far is the facility from public transportation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How far is the facility from where mothers live/work?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Facility hours</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During what hours is the clinic open?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a sign listing services and clinic working hours?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are time convenient for working parents and their partners?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Facility environment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the facility provide a comfortable setting?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a counselling area that offers both visual and auditory privacy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there an examination room that provides both visual and auditory privacy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are family members (e.g., grandparents, male partners) made to feel comfortable when they accompany mothers attending the clinic with their babies?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Staffing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all healthcare providers trained to conduct DBS procedure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all healthcare providers trained in ART?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have all staff members (including data clerks, pharmacists, receptionists, etc.) received orientation about infant HIV testing services?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do healthcare providers show respect for caregivers/babies affected by HIV?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there job aids available to help healthcare providers in their daily work with caregivers?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Services provided</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are mother/babies offered integrated services? Describe.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the following services provided to clients directly (note if through referral):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Questions to assess accessibility/client-friendliness

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Comments/recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Comprehensive care for HIV-exposed babies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ART for mothers and babies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Adherence preparation and ongoing adherence assessment &amp; counselling (at each visit)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Care for mothers, such as ART, family planning, STI screening and treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Psychosocial counselling and support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Nutrition counselling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Laboratory tests (CD4, other HIV tests)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Educational activities

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Comments/recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do caregivers request services other than the ones offered? Which ones?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a formal referral system for services not provided at the clinic?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a tracking and follow-up plan in place for clients who do not return?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there outreach services, especially targeting clients lost to follow-up? Explain.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Client involvement

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Comments/recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are caregivers involved in decision-making about how services are delivered?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What ways are there for caregivers to give feedback to clinic staff?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Supportive policies

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Comments/recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do clear, written guidelines or standard operating procedures (SOPs) exist for services?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do written procedures exist for protecting client confidentiality?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questions to assess accessibility/client-friendliness</td>
<td>Answer</td>
<td>Comments/recommendations</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>--------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Are records stored so that confidentiality is ensured?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is spousal consent ever required? In what cases?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Administrative procedures**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Comments/recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the registration process private so that others cannot see or hear?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can clients be seen without an appointment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long do clients normally have to wait?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is the average time allotted for client/healthcare provider interaction?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fees**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Comments/recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>If there are fees, are they affordable?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OTHER?**

Appendix 10: Supervision Checklist for Staff and Programme Managers

This checklist, which was originally developed by ICAP for the Zambia Ministry of Health, is offered as an aid to support supervision for infant HIV testing services. This document was designed for use by site supervisors as a way of monitoring infant HIV testing activities and developing a remediation plan as part of routine quality improvement activities. In comparison, Appendix 11 was designed for site monitoring by national and/or subnational programme officers.

The goals of supportive supervision are to:

• Obtain valuable information on programme functioning and quality.
• Facilitate participatory problem solving.
• Assure the programme successfully meets the needs of infants/children and their families.
• Improve staff performance and the quality of infant HIV testing services by providing technical support and acknowledging healthcare providers’ contribution to the success of the programme.

When infant HIV testing services are initially implemented, routine quality assurance (QA) checks should be made bi-weekly and supervisory visits should occur monthly for at least 6 months. When services are firmly in place and running smoothly, monthly QA checks and quarterly supervision should be adequate.

Instructions

Through direct observation, interviews and/or review of data:

• Answer each question with a “yes” or “no”. (Note: It may not be possible or necessary to complete every section of this tool every time an evaluation occurs.)
• Assign one point for each “yes” response, and zero points for each “no” response.
• Tally the number of points by section and compare with the total number of points possible for that section.
• Acknowledge the team’s strengths.
• Discuss areas for improvement (if any) and formulate a plan to correct problems.
• If no problems were identified, continue routine QA activities.
• If problems were identified, re-evaluate after taking corrective action.
  • Acknowledge improvements (if any).
  • Re-evaluate corrective action plan if no improvements are seen.
### 1. General information

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are reference materials on site and accessible, including:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• National guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• RDT instructions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Counselling cue cards and/or other job aids</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• DBS instructions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are staff members not directly involved in delivery of infant HIV testing services trained in how to take a DBS specimen? Are they aware of the rationale for these services? Note any circumstances that could inform plans for future training. Briefly interview representative staff and stakeholders, such as:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Nurse and/or midwife</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Community healthcare provider or lay provider</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Clinical officer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pharmacist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Laboratory technician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The number of staff represented will vary depending on the size and type of facility.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of points this section:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of points possible: 2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2. Questions on staffing and training

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were staff provided with an infant HIV testing orientation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a specific infant HIV testing coordinator or director been identified?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have the staff who will implement infant HIV testing services been trained in specific skills, e.g., DBS testing, heel stick, pre- and post-test counselling, etc?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have healthcare providers who will conduct post-test counselling been identified and trained.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If lay providers have been recruited, are their roles clear? Is their line of supervision clear?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there sufficient healthcare providers to</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 2. Questions on staffing and training

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implement infant HIV testing services for all HIV-exposed infants?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a designated person for data reporting and collection, or if not, are staff who collect data trained to fill out forms?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of points this section:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total number of points possible: 7

### 3. Physical facility

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are supplies kept in a secure location?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there adequate space for testing and counselling?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the space allow for privacy for individual counselling?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a table available to conduct tests?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there sufficient equipment to conduct activities, e.g., beds, chairs for waiting room, etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the rooms, equipment, and physical space kept clean?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a system at the testing location for disposing of hazardous materials (e.g., sharps containers) and rubbish?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of points this section:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total number of points possible: 7

### 4. Supplies

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments/Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were sufficient supplies available to ensure universal precautions are followed, e.g., gloves, etc?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were there sufficient supplies of other needed materials, e.g., sterile gauze pads, timers, etc?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were there sufficient numbers of RDT kits (not out of date) available?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were there sufficient numbers of DBS cards/test kits (not out of date) available?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were expired supplies kept separate from those that are to be used?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is a system in place to ensure that stock outs do not occur?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there working systems to manage receiving supplies and transport of DBS samples to central labs for testing?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of points this section:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Supplies

| Total number of points possible: 7 |

5. Observation of testing and counselling

### 5a. Pre-test information session

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments/Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the healthcare provider explain that testing is routine?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider explain how the test will be done?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider explain what a positive/negative test result means?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider explain when test results will be available?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider ask if the client had questions?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total number of points this section: 5

Total number of points possible: 5

### 5b. RDT and NAT procedures

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments/Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the counsellor use the correct HIV testing procedure (in accordance with the testing algorithms)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For DBS only: was the specimen labelled correctly?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the blood sample collected correctly? (Heel stick for children 9kg or under; toe if over 9kg; finger prick for those over 2 years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the puncture site warmed and sterilized?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the blood applied correctly to the test strip/filter paper?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were the caregiver and child given instructions and support?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were universal precautions used consistently?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was RDT/DBS procedure conducted according to instructions?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For RDT only: Were the results correctly interpreted?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For DBS only: Was the specimen air dried for at least 3 hours?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For DBS only: Was glassine paper inserted between dried filter paper cards and desiccant packets inserted appropriately?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For DBS only: Was the laboratory request form properly completed and placed with the specimen?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total number of points this section:
### 5b. RDT and NAT procedures

<table>
<thead>
<tr>
<th>Total number of points possible:</th>
<th>RDT: 8; DBS: 11</th>
</tr>
</thead>
</table>

### 5c. Post-test counselling

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the healthcare provider explain what the test result meant?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider discuss infant feeding and the implications of breastfeeding on result (if applicable)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider discuss if cotrimoxazole should be initiated/continued/discontinued?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider ask about care and treatment for the mother and other family members?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider assess caregiver’s understanding of the results and follow-up plan?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the healthcare provider use listening and learning skills, e.g., asking open-ended questions, maintaining a non-judgmental attitude, showing empathy?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were appropriate referrals made?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total number of points this section:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of points possible:</td>
<td>7</td>
</tr>
</tbody>
</table>

### 6. Referral linkages and systems

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are linkages established that include referral mechanisms, appointment tracking and follow-up with: Paediatric HIV treatment?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Adult HIV treatment?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Reproductive health and family planning services?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Under-5 clinic/immunization services?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Community-based services?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Are healthcare workers knowledgeable about how to make referrals and know of the potential places where caregivers and children can be referred? |       |      |          |

| Is there a tracking and communication system in place for attendance at appointments for: NAT results? |       |      |          |

<table>
<thead>
<tr>
<th>Total number of points possible:</th>
<th></th>
</tr>
</thead>
</table>
- For repeat testing and counselling (e.g., at 9 months and again 3 months after breastfeeding has ended)?
- For testing of partner(s) and sibling(s)?

Does the facility have a working linkage with the laboratory for infant virological testing?

Are NAT results received within 2–4 weeks?

**Total number of points this section: __________________**

**Total number of points possible: 5**

### 7. Data collection and use

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the designated registers/databases, Under-5 card, Mother’s card, and medical record correctly completed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the weekly/monthly report for PMTCT/infant HIV testing correctly completed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the site conduct and document QI activities?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have all monthly monitoring forms been submitted in the past year?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total number of points this section: __________________**

**Total number of points possible: 4**

### 8. Client-exit interview (the caregivers are the clients)

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes-1</th>
<th>No-0</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you feel that you were respected by the counsellor, regardless of your age or HIV status?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the facility clean and comfortable?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did the counsellor explain testing in a way that you understood?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were you provided with a private, confidential space for your post-test counselling?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you understand what the test result mean?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you understand what the next steps are for you and your child?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you feel comfortable enough to ask any questions that you had?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did you get referrals from the healthcare provider?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you plan to follow up on the referrals, e.g., going to get care and treatment for your child and/or yourself?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What suggestions do you have for improvement?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of points this section:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of points possible: 10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The HIV-exposed infant core essential elements (CEE) are listed in the table below.

<table>
<thead>
<tr>
<th>CEE number</th>
<th>Abbreviated Title</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>S_04_15*</td>
<td>Early Infant Diagnosis Provided to Caregiver</td>
<td>All HIV-exposed infants (HEIs) have a specimen collected for early infant diagnosis (EID) and infant virologic testing (IVT). There is documented return of HIV results to caregivers within one month of sample collection.</td>
</tr>
<tr>
<td>S_04_16</td>
<td>Tracking HIV-Exposed Infants</td>
<td>Each site providing services for HIV-exposed infants (HEIs) has a standard procedure for identifying and tracking HEIs who have missed an appointment. The tracking system includes procedures for patient identification and tracking; standardized documentation showing evidence of more than one attempt to bring the patient back into care, and results of tracking efforts.</td>
</tr>
<tr>
<td>S_04_17*</td>
<td>Collection of a Second Specimen for Confirmatory Testing</td>
<td>All infants with an initial positive virologic test result (from either Laboratory or Point of Care Testing) have a second specimen collected for confirmatory testing.</td>
</tr>
<tr>
<td>S_04_18</td>
<td>CTX for HIV-Exposed Infants</td>
<td>All HIV-exposed infants (HEIs) initiate cotrimoxazole (CTX) by eight weeks of age.</td>
</tr>
<tr>
<td>S_04_19*</td>
<td>HEI Follow-up and Final HIV Status</td>
<td>All HIV-exposed infants (HEIs) are tracked through the end of breastfeeding and have a documented final HIV outcome by 24 months of age.</td>
</tr>
<tr>
<td>S_04_20</td>
<td>Enrollment of HIV-Infected Infants into ART Services</td>
<td>All HIV-infected infants are enrolled into ART services.</td>
</tr>
<tr>
<td>S_04_21</td>
<td>Supply Chain Reliability (Early Infant Diagnosis) DBS or POC</td>
<td>Each PMTCT site has a reliable supply of Early Infant Diagnosis (EID) collection supplies for specimens (including dried blood spot (DBS)) obtained for conventional laboratory-based testing or for point-of-care testing (POCT) and has fully functional platforms for testing.</td>
</tr>
</tbody>
</table>

* Indicates that this is a new CEE as of SIMS, v 4
CEE’s in bold are required, all others are elective.

Additional information about all of the above CEEs can be found in the PEPFAR Site Improvement Through Monitoring (SIMS) Site Assessment Tool, Version 4.0 (released on November 30, 2018), available at: [https://www.pepfar.gov/documents/organization/288390.pdf](https://www.pepfar.gov/documents/organization/288390.pdf)
The SIMS tools were designed for use by national and subnational programme officers to support standardized monitoring of all sites in their jurisdictions. It may also be used by site managers as an internal audit tool.

The Site Improvement Through Monitoring (SIMS) Site Assessment Tool also includes the CEEs for commodities management, data quality, care and treatment, PMTCT, voluntary medical male circumcision, AGYW, GBV and OVC, HTS, TB treatment, methadone or buprenorphine medication assisted treatment, laboratory, and blood safety. PEPFAR also has a PEPFAR Site Improvement Through Monitoring (SIMS) Above-Site Assessment Tool, Version 4.0 (also released on November 30, 2018) that includes programme-level CEEs. Some of those CEEs are directed to subnational programme managers.
Appendix 12: Managing Indeterminate Test Results: Standard Operating Procedure

Notes:
1. Refer to 2016 WHO ARV Consolidated guidelines.
2. Do not report as positive nor initiate ART, but maintain prophylaxis per current guidance.
3. Repeat samples should be prioritized in the laboratory.
4. Repeated indeterminate results in two separate samples should, together with clinical information, be reviewed by a team of laboratories, clinicians paediatricians, complex case experts (if possible), and caregivers. Infants should be actively tracked to ensure follow-up and retention.

Source: WHO, 2018 (3).
Appendix 13: Criteria for Introducing SMS Printers

The following infrastructure requirements must be met to make implementation of SMS printers possible.

- **Electricity**
  - The SMS printer should remain switched on and plugged into a socket at all times.
  - When electricity is not available, a fully-charged SMS printer has 8 hours worth of battery life.
  - When electricity is not available, a solar panel can be used to power the device.

- **Connectivity**
  - Access to the SMS network is required to receive results at the facilities, which means that the SIM card in the device should be registered.
  - Results that are delivered from the central facility during a network outage will arrive when connectivity is restored.
  - The network should also be used to transmit results from a country’s testing laboratories to a central data collection site (e.g., MOH’s LIMS system) to aggregate national data.

- **Facility Conditions**
  - The SMS printer should be kept in a secure, confidential area outside of direct sunlight and away from rodents. The SMS printer uses thermal paper to print (not ink), so printed results must be kept out of direct sunlight/away from heat sources.

Site Selection
As it is not possible or necessary to place an SMS printer at every sample collection site, a system for prioritizing placement must be in place before devices are distributed. Important considerations for site selection include:

- infant HIV testing testing volumes
- Distance from the testing laboratory
- Baseline turnaround time

Clinton Health Access Initiative (CHAI)
### Appendix 14: Clinic Sample Transport Log

**Clinic:** ______________________________________________________   **Date:** ____/____/____

<table>
<thead>
<tr>
<th>Participant ID: Name and ID# only</th>
<th>Sample Type</th>
<th># of Samples Collected</th>
<th>Test Requested</th>
<th>Sample Collection Verification</th>
<th>Receiving Lab: Sample Rejected</th>
<th>Date Results Received at Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: ____________________________</td>
<td>□ Whole Blood</td>
<td>□</td>
<td>□ HIV RNA (VL)</td>
<td>□ Yes, Reason for rejection:</td>
<td>□ Clotted</td>
<td></td>
</tr>
<tr>
<td>ID#: ____________________________</td>
<td>□ DBS</td>
<td>□</td>
<td>□ HIV Infant Testing</td>
<td></td>
<td>□ Hemolyzed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Plasma</td>
<td>□</td>
<td></td>
<td></td>
<td>□ Insufficient volume</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Other</td>
<td>□</td>
<td></td>
<td></td>
<td>□ Other:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Type ________</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name: ____________________________</td>
<td>□ Whole Blood</td>
<td>□</td>
<td>□ HIV RNA (VL)</td>
<td>□ Yes, Reason for rejection:</td>
<td>□ Clotted</td>
<td></td>
</tr>
<tr>
<td>ID#: ____________________________</td>
<td>□ DBS</td>
<td>□</td>
<td>□ HIV Infant Testing</td>
<td></td>
<td>□ Hemolyzed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Plasma</td>
<td>□</td>
<td></td>
<td></td>
<td>□ Insufficient volume</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Other</td>
<td>□</td>
<td></td>
<td></td>
<td>□ Other:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Type ________</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name: ____________________________</td>
<td>□ Whole Blood</td>
<td>□</td>
<td>□ HIV RNA (VL)</td>
<td>□ Yes, Reason for rejection:</td>
<td>□ Clotted</td>
<td></td>
</tr>
<tr>
<td>ID#: ____________________________</td>
<td>□ DBS</td>
<td>□</td>
<td>□ HIV Infant Testing</td>
<td></td>
<td>□ Hemolyzed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Plasma</td>
<td>□</td>
<td></td>
<td></td>
<td>□ Insufficient volume</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Other</td>
<td>□</td>
<td></td>
<td></td>
<td>□ Other:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Type ________</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**To be completed by designated clinic packing staff**  
- Nurse  
- Lab  
- Assist  
- Phlebotomist

**Verification by Clinic Manager**  
Date: ____/____/____  Time: __:__

- Requisition form complete? □ Yes or □ No  
- Total number of tubes confirmed? □ Yes or □ No  
- Sample packed according to standard operating procedure? □ Yes or □ No  
- Ice pack frozen? □ Yes or □ No  
- Data logger properly placed in cooler? □ Yes or □ No  

**To be completed by designated driver for transport**  
Pick-up date: ____/____/____  Pick-up time: ____/____/____

- Confirm lab request form is available? □ Yes or □ No  
- Confirm Transport log is available? □ Yes or □ No

**To be completed by the receiving Lab**  
(LAB NEEDS TO RETAIN A COPY)

- Receiving Lab: ___________________  
- Lab receipt date: ____/____/____  Lab Receipt Time: __:__

- Received lab request form with shipment? □ Yes or □ No  
- Received transport log with shipment? □ Yes or □ No

**Confirm packaging condition:**

- Ice pack was received frozen? □ Yes or □ No  
- Data logger in cooler box? □ Yes or □ No

**Receiving staff signature:** ___________________
Additional Resources

ASLM website, Viral Load Scale Up tools page (which also includes materials on infant HIV testing): http://www.aslm.org/resource-centre/hiv-viral-load-testing/hiv-viral-load-scale-tools/

Important tools include:

- Guidance for developing a specimen transport and referral system for Viral Load and Infant Virologic HIV Diagnostic Testing Networks (link is near the bottom of the home page)
- HIV Viral Load and Early Infant Diagnosis Scorecard (click on the “HIV Viral Load Scorecard” link near the bottom of the home page)

ForLab. This is a diagnostic forecasting software developed by the United States Agency for International Development (USAID), John Snow Inc, Supply Chain Management System, and the Clinton Health Access Initiative and suitable for national level planning. ForLab utilizes product consumption data, service statistics data, and demographic/morbidity data for forecasting laboratory commodity needs. ForLab is available for download from: http://www.forlabtool.com/

IATT. Option B/B+ Toolkit, Updated Version May 2015. This is a 10-module toolkit for countries transitioning to Option B/B+. The assessment tools and checklists, although designed for countries transitioning to Option B/B+, can be used to support national decision making for scaling up universal ART. http://emtct-iatt.org/toolkit/


Tools for HIV-Exposed Infant Care and Infant Virologic Testing. Developed by CDC-Atlanta Maternal Child HIV Branch and International Lab Branch, in collaboration with partners, these tools support healthcare providers and laboratorians to provide services to HIV-exposed infants, including infant virologic testing. The tools include:

- Flipchart on care of HIV-exposed infants
- Job aid for clinics on the collection of DBS
- Job aid for laboratories working with DBS
- Educational training videos on DBS collection, drying and packaging

http://childrenandaids.org/HEI_Toolkit

HIV Point-of-Care Diagnostics Toolkit. Includes Key Considerations for Introducing New HIV Point-of-Care Diagnostic Technologies in National Health Systems, as well as practical tools and guidance. This toolkit was developed with UNITAID support. http://childrenandaids.org/poc-toolkit-page

USAID: AIDSFree. This website aims to improve the quality and effectiveness of high impact, evidence-based HIV interventions to meet country-specific goals and objectives. The early infant diagnosis archive is at: https://aidsfree.usaid.gov/resources/vl-eid

References

3. WHO. HIV Diagnosis and ARV Use in HIV-Exposed Infants: A Programmatic Update. 2018.
26. The CE Marking, which stands for "Conformité Européene", means that a product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. CE Marking on a product ensures the free movement of that product within the European Free Trade Association and European Union.
28. CDC. NJ. Memorandum: consideration for the use of two point-of-care assays (Alere™ q HIV-1/2 Detect and Xpert®HIV-1 Qual) in resource-limited settings. 2016.